SPRING 1996

TRIALS SEARCH GUIDE

HIV Clinical Trials in California

Northern California Edition

COMPILED BY THE COMMUNITY CONSORTIUM

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Introduction

Clinical trials are often the first place people with HIV can gain access to promising new medical treatments. They are an important option for anyone with HIV. Unfortunately, learning about clinical trials can be difficult and confusing. That's where Trials Search can help.

Trials Search is a database of open HIV clinical trials in California. Trials Search matches clinical trial entry requirements with an individual's medical history and current health status and produces a personalized list of studies for which he or she might qualify. Trials Search is a free service. Call 1-800-492-5777 for more information or to receive a questionnaire.

The *Guide to HIV Clinical Trials in California: Northern California Edition*, includes information about all clinical trials currently enrolling patients of which we are aware. No endorsement is made of any trial described herein. Every reasonable effort has been made to ensure that the information presented in the Guide is accurate, comprehensive and up-to-date. However, eligibility and other criteria are subject to change, and trials may close to patient enrollment at any time.

The Community Consortium welcomes information about all clinical trials available throughout California for inclusion in *Trials Search*. Any trial which has been reviewed and approved by an Institutional Review Board may be included. Institutional Review Boards are committees which are set up to review research involving human subjects to ensure that studies are ethical and scientifically sound. Anyone with information appropriate for publication is asked to call the Consortium at (415) 476-5777 or (800) 492-5777.

Trials Search and the database of California HIV Clinical Trials are also available on the Internet at:

http://www.library.ucsf.edu/aidstrials

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Trials search guide.

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Research staff at more than 40 trial sites who furnished the bulk of the information contained in the Guide. Without their considerable expertise and generous contribution of time and energy this project would not have been possible.

The following publications for their reliability and usefulness:

• *AIDS/HIV Treatment Directory* published by the American Foundation for AIDS Research (AmFAR) as a general resource.
• *Bulletin of Experimental Treatments for AIDS (BETA),* from the San Francisco AIDS Foundation, for information on patient assistance and expanded access programs and the California AIDS Drug Assistance Program (ADAP).
• *Treatment Issues* from the Gay Men's Health Crisis (GMHC) for the Glossary of Medical Terms which is a reference and basis for some of our glossary entries. The online Guide uses the GMHC Glossary as a whole.

An Association of Bay Area
HIV Health Care Providers

The Community Consortium is affiliated with the
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How to use this Guide

The **Trials Search Guide** is written for people who are living with HIV disease and for their health care providers. It should be used as one resource among many in learning about HIV disease. The **Guide** will probably be most useful to people who already know something about their own health and about HIV. If you think you need to learn more, talk to your health care provider and contact some of the Resources beginning on page 71.

Understandable language

One of the stumbling blocks for many people in learning about HIV and clinical trials is confusing "medical jargon". We have tried to avoid using technical language whenever possible, but sometimes there is no simple way to describe technical information. If you come across a word or idea that you don't understand, you can check the Glossary on page 73. It may be helpful to discuss any remaining questions with your health care provider, or the contact person listed for the clinical trial. More information will also be available from one or more of the Resources listed on page 71.

Questions about clinical trials, and issues for special groups

To answer some important questions about clinical trials, and about who can join a clinical trial, we have included sections on common questions about clinical trials, how to join a clinical trial, and issues about clinical trials for women, children, youth and people who use injection drugs. These sections are found on pages 55 through 65.

Trial Finder and Trial Descriptions

The 109 trials listed in the **Guide** are arranged by the disease or condition being studied, or by the group of people for whom the study is intended. Trial Finder on pages 3 - 6 is a quick reference for trials you may be interested in.

If you are interested in a certain drug or treatment for a particular disease, you can also look it up in the Index, starting on page 77. The Index will tell you which page to turn to in the **Guide**.

(continued)

How to use this Guide

For each clinical trial, we include the following information:

Title: This is the official name of the trial. Some trials also have letters or numbers given in parentheses after the title. For example, ACTG 244 means this is AIDS Clinical Trials Group study number 244.

Type of Drug: For the anti-HIV drugs we give information about what type of drugs are being tested. The different types of anti-HIV drugs attack the virus in different ways. Older anti-HIV drugs such as AZT, ddI, ddC and d4T are all a type of drug called a "nucleoside analog". Some newer drugs are called "protease inhibitors" and "non-nucleoside reverse transcriptase inhibitors".

Purpose: This is what the researchers are trying to learn from the trial. Below are a few of the most common reasons why studies are done.

- To learn if a drug is safe for people to take.
- To learn if a drug works.
- To compare two or more drugs.
- To compare two or more doses of the same drug.

About the study: This section describes what will happen during a trial, from the patient's perspective. We tell you how long the trial lasts, if you will know what drugs you are taking, how the drug is given (for example, pill, liquid or injection), if there are an unusual number of required visits to the clinic, or if you need to stay in the hospital.

Required: These are the entry requirements that you must meet before you can join the study. These are sometimes called "inclusion criteria." We have space to list only a few of the most important entry requirements. In many cases, there will be others.

Not allowed: You cannot join the study if you fit any of these criteria. These are sometimes called "exclusion criteria." Again, only the most important exclusion criteria are included. You may not be able to join this particular study because there is a good chance that you would be harmed by the study drug. Researchers examine your medical history and your laboratory tests to make sure you are not at "high risk" for experiencing harmful side effects. Many clinical trials require that your laboratory tests be "within normal limits," or at least in a safe range. This is to make sure you don't already have a medical problem that might become worse if you take the drug.

Women who are pregnant or breastfeeding may also not be able to join a clinical trial. This is because it is not known if taking the drug will harm the baby. Usually, women who have sex with men, and men who have sex with women, must agree to use birth control while they are in the study.

Location: This is where you need to go to participate in the study (the study "site"). We also give you the name of the person to call if you are interested. In most cases, you don't have to be a patient at the hospital or clinic where the study is located in order to join the study. For some studies, your doctor must contact the site first.

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New

1. HIV Infection: AR-177

Title:

A Phase I Study to Determine the Safety and Pharmacokinetic Profile Following Single Doses of AR-177

Type of treatment:

AR-177: antiretroviral

Purpose:

To see how safe different doses of the new drug AR-177 are and to see how AR-177 is processed by the body.

About the study:

This is a dose-escalating study. This means that the first group of patients entering the study will receive the lowest dose of AR-177. If no bad side effects are observed, the next group of patients will receive a higher dose of AR-177 and so forth until the maximum dose has been given. Patients will know which dose they are receiving. AR-177 is given by infusion into a vein once over a two hour period. Study follow-up lasts 14 days. AR-177 is a new type of drug which acts against HIV in a different way than any other medication currently available. Participants are paid $100 for completing the study.

Required:

- CD4 cell (T-cell) range: at least 200
- HIV positive
- At least 18 years old

Not allowed:

- Any previous or current AIDS-defining illness
- Substance abuse including tobacco (within the past 3 months)
- Pregnant or nursing females

Location:

UCSF AIDS Program at SFGH/ICTG
Jose Pacheco
(415) 476-9296, ext. 84101

New

2. HIV Infection: Viral Load Analyses

Title:

CPCRA 036: A Randomized Study of the Clinical Effects of Initiating or Changing Antiretroviral Therapy Based on Plasma HIV RNA Quantitation Compared With Initiating or Changing Therapy Based on Current Clinical Practice Alone

Type of treatment:

Observational

Purpose:

To see if using HIV viral load (bDNA lab tests) in addition to current clinical care (CD4 T-cell counts and/or disease progression) in deciding when to start or change therapy is more effective than deciding to start or change therapy based on current clinical care alone.

About the study:

Patients are assigned by chance to a decisionmaking plan for starting or changing medication based on their viral load (bDNA blood tests) in addition to current clinical care versus decision-making plans based on current clinical are alone. Patients and their doctors will know to which plan they have been assigned. All patients have 2 baseline viral load tests done prior to study entry. Those patients assigned to the viral load plan will have viral load tests done every four months. Some patients in the current clinical practice plan will also have viral load tests every 4 months but will not know the results until the end of the study. The study lasts 2 1/2 years.

Required:

- CD4 cell (T-cell) range: 100 to 300
- HIV positive
- 13 years of age or older

Location:

Community Consortium
Ask your health care provider
(415) 476-9554

New

3. HIV Infection: TN

Title:

A Phase I/II Study of the Safety, Immunogenicity, and Anti-HIV Effects of TN Antigen Administered with Adjuvants in HIV Positive Individuals

Type of treatment:

TN Antigen: immune modulator

Purpose:

To learn about the safety and effectiveness of immune activation of the TN structure on HIV.

About the study:

Patients are assigned by chance to receive TN taken from red blood cells versus TN that is man-made. Patients and their doctors will know which type of TN they are receiving. TN is a carbohydrate that is thought to have an anti-HIV effect. TN is given by an injection under the skin four times over 13 weeks. Study visits are every 2-3 weeks and the study lasts four months. Patients will have their blood type done at a screening visit and some patients must have type B or AB blood.

Required:

- CD4 cell (T-cell) range: at least 200
- HIV positive

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

New

4. HIV Infection: Saquinavir

Title:

NV15182: A Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Multicenter Study with Open-Label Extension of the Safety and Activity of Saquinavir Soft Gelatin Capsule Formulation (Saquinavir SGC) in Combination with Other Antiretroviral Drugs

Type of treatment:

Saquinavir: antiretroviral, protease inhibitor

Purpose:

To learn how safe and effective Saquinavir SGC is in combination with other antiretrovirals to fight HIV.

About the study:

Patients are assigned by chance to receive either Saquinavir SGC or placebo, while continuing their current antiretroviral drug(s). Neither patients nor their doctors will know which they are taking until the study ends. After 16 weeks, all patients will be given the choice of receiving open-label (real) Saquinavir SGC for 44 weeks. If patients experience an AIDS-defining illness during the first 16 weeks, the patient will have the choice to continue the study on open-label Saquinavir. Patients must stay on the same antiretroviral therapy for the first 16 weeks but may then change therapy for the open-label portion of the study. Study visits will be on weeks 2, 4, 8, 12, 16 for the blinded portion and once a month for the open-label portion. The study lasts 60 weeks.

Required:

- CD4 cell (T-cell) range: 500 and below
- HIV positive
- At least 13 years old

Not allowed:

- Ever taken Saquinavir
- Any active opportunistic infections
- Chronic diarrhea
- Pregnant or nursing women

Location:

Camino Medical Group
Sandra Odenheimer, NP
(408) 730-4298

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

Davies Medical Center HIV Institute
Patricia O'Connor, RN
(415) 565-6649

New

5. HIV Infection: 3TC, AZT, d4T, ddI

Title:

ACTG 306: A Phase II, Randomized Study of the Antiviral Activity and Resistance Interactions of Lamivudine (3TC) In Combination With Zidovudine (ZDV), Stavudine (d4T), or Didanosine (ddI) Versus Monotherapy With ddI or d4T in HIV-infected Individuals With 200-600 CD4 Cells/MM3 and No Previous Nucleoside Experience

Type of treatment:

3TC, AZT, d4T, ddI: antiretroviral, reverse transcriptase inhibitor

Purpose:

To compare combinations of these drugs on lowering the amount of HIV in your blood and to learn which combinations will show resistance to HIV.

About the study:

Patients in this study will be assigned by chance to be in the ddI or d4T part of the study. Patients will then be assigned by chance to ddI/d4T/placebo (depending on their first assignment) plus AZT (or placebo) and 3TC (or placebo). All patients will be receiving at least one but not more than 2 real drugs. Neither patients nor their doctors will know which they are receiving until the study ends. Study visits will be every month for the first 6 months, then every 2 months for the next 6 months. Patients will be followed for 48 weeks.

Required:

- CD4 cell (T-cell) range: 200 to 600
- HIV positive
- 12 years of age or older

Not allowed:

- History of peripheral neuropathy
- History of acute or chronic pancreatitis
- Ever taken AZT, ddI, ddC, d4T or 3TC
- Pregnant women

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

Kaiser San Francisco - HIV Research
Gretchen Van Raalte, RN, MS
(415) 202-3482
(Kaiser Health Plan members only)

New

6. HIV Infection: Indinavir Sulfate, AZT, 3TC

Title:

ACTG 320: A Randomized, Double-Blind, Phase III Study of Indinavir Sulfate (IDV) with Open-Label Zidovudine (ZDV) and Lamivudine (3TC) in Subjects with HIV Infection with CD4 Cell Counts of 200 or Less and 6 Months or More of Prior ZDV Experience

Type of treatment:

3TC, AZT: antiretroviral, reverse transcriptase inhibitors
Indinavir: antiretroviral, protease inhibitor

Purpose:

To learn about the safety and effectiveness of IDV when given in combination with AZT (ZDV) and 3TC.

About the study:

Patients are assigned by chance to receive either IDV with AZT and 3TC or placebo with AZT and 3TC. Neither patients nor their doctors will know whether they are receiving IDV or placebo until the study ends. All drugs are taken by mouth. In some cases, patients will be able to switch from AZT to d4T after the first 24 weeks of study treatment. In some cases, patients will be able to switch from study treatment to open-label (real) IDV. Study visits and blood draws take place at screening, pre-entry, entry and weeks 4 and 8, then every 8 weeks until the study ends.The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: 200 or less
- At least 18 years old
- Six months or more of AZT therapy at any time before study entry.

Not allowed:

- More than one week cumulative use of 3TC
- Use of rifampin or rifabutin within 14 days before starting the study
- Unable to tolerate at least 600 mg/ day of AZT
- History of Pancreatitis
- Acute hepatitis within 30 days before starting this study
- Diarrhea for 15 out of the 30 days before starting this study
- Women who are pregnant or breastfeeding.

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

New

7. HIV Infection: 3TC and Viral Load (Observational)

Title:

An Observational, Non-Randomized, Open-Label Study of the Degree and Duration of the Effect of 3TC on bDNA Levels in Persons Who Add 3TC to a Stable Antiretroviral Regimen Other Than AZT Monotherapy or Protease Inhibitors

Type of treatment:

Observational study

Purpose:

To see what effect adding 3TC has on bDNA (viral load) studies for patients who are taking antiretroviral medications other than AZT or protease inhibitors.

About the study:

Patients who enroll on this study must already be taking antiretroviral medication other than protease inhibitors or AZT by itself (AZT in combination with other antiretrovirals, such as ddI, ddC or d4T is allowed). They must also be adding 3TC to their treatment regimen. Patients will have study visits at screening, baseline, weeks four, eight and twelve, and then every eight weeks until the end of one year. Patients will have bDNA blood tests done at the screening and baseline visits and periodically throughout the study, for a total of ten tests. Patients must be able to obtain all antiretroviral medication(s), including 3TC, by prescription. No study medications will be provided for this study. The cost of bDNA testing will be covered by the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 13 years old
- Beginning therapy with 3TC
- bDNA (viral load) level: at least 50,000 copies within two weeks prior to starting 3TC
- Must be taking antiretroviral medication other than AZT by itself or protease inhibitors for at least 8 weeks before starting 3TC

Not allowed:

- Ever taken 3TC
- Any vaccination within 45 days prior to enrollment

Location:

HIVCare, St. Francis Medical Center
Sher Vieira
(415) 353-6215

New

8. HIV Infection: rgp160 Vaccine

Title:

ACTG 246: A Phase I/II, Double-Blind Controlled Trial to Determine the Safety and Immunogenicity of HIV-1 MN rgp160 Immuno Ag Vaccine Therapy in HIV-Infected Individuals With Greater Than or Equal to 500 CD4 T-Cells

Type of treatment:

HIV Vaccine

Purpose:

To see if rgp160 is safe and effective in producing antibodies in people with HIV. Effectiveness will be measured by CD4 (T-cell) counts and skin test reactions.

About the study:

Patients will be assigned by chance to receive rgp160 vaccine or placebo. Both are given as injections into a muscle. Injections are given every four weeks for the first seven months, and then every eight weeks until one year after the last patient has been enrolled. Study visits will occur at the same time as injections. Patients will be in this study until one year after the last patient has enrolled.

Required:

- CD4 cell (T-cell) range: at least 500
- At least 13 years old
- HIV positive
- Less than 12 months prior use AZT

Not allowed:

- Ever taken any other antiretroviral (ddI, ddC, d4T, 3TC)
- Taken AZT for more than 12 months
- Any HIV vaccine
- Women who are pregnant or nursing
- Chronic diarrhea
- Allergy to any vaccine component

Location:

Stanford University Medical Center
Mary Rinki, RN
(415) 723-6231

New

9. HIV Infection: IL-12

Title:

A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalating, Multiple-Dose Study of the Safety of Subcutaneous Recombinant Human Interleukin-12 (rhIL-12) in HIV-Infected Subjects

Type of treatment:

Interleukin-12: immune modulator

Purpose:

To learn about the safety of Interleukin-12 at three different doses

About the study:

Patients are assigned by chance to receive the lowest of three doses of IL-12 or placebo. If no bad side effects are observed, the next patients to enter the study are assigned by chance to the middle dose of IL-12 or placebo. The last group of patients to enroll will receive either the high dose of IL-12 or placebo. IL-12 and its placebo are given by injection under the skin. Injections are given twice a week and the study lasts 16 weeks.

Required:

- CD4 cell (T-cell) range:100 to 500
- HIV RNA 5000 equivalents or greater (to be tested by the researchers)
- HIV positive
- Must be on a stable combination of antiretrovirals for 6 weeks before the study
- Between 18 and 60 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Any AIDS-defining opportunistic infections (except PCP which has been treated)

Location:

UCSF AIDS Program at SFGH/ICTG
Jose Pacheco
(415) 476-9296, ext. 84101

New

10. HIV Infection: Tucaresol

Title:

Protocol 110-101: A Multicenter, Open-Label, Dose-Escalation, Pilot Study of Tucaresol (589C80) in HIV-Infected Patients with Moderate Immune Suppression (CD4+ Cell Counts of 300-500/mm^3), Incorporating Amendments 1 & 2

Type of treatment:

Tucaresol: immune modulator

Purpose:

To see how safe and effective the new drug tucaresol is for treating HIV infection. To compare the safety and effectiveness of different doses and different dosing schedules on the amount of HIV in the blood (viral load). To learn how the body processes and eliminates tucaresol.

About the study:

This is a dose-escalation or dose-ranging study. This means that the first patients to enroll will receive the lowest dose of tucaresol. If there are no bad side effects, the next patients will enter the study at a higher dose. This plan continues until the highest dose researchers plan to study has been given.Study visits are every week and the study lasts 16 weeks. Participants are paid $365 for completing the study.

Required:

- CD4 cell (T-cell) range: 300 to 500
- HIV positive
- At least 18 years old
- Must be on antiretroviral therapy for at least 3 but not more than 12 months and maintain that same therapy throughout the study

Not allowed:

- Any history of an AIDS-defining illness including KS
- Prior use of HIV vaccines, IL-2, alpha interferon, G-CSF, GM-CSF, or any experimental anti-HIV therapy
- current hepatitis B or past hepatitis C
- History of significant respiratory disease, ie., asthma, emphysema, etc.
- Abnormal EKG or significant coronary or cardiovascular disease
- Women who are pregnant or nursing
- Current use of illegal street drugs

Location:

ViRx, Inc.
Rick Fallis
(415) 353-5623

11. HIV Infection: AZT, ddI

Title:

ACTG 276: A Multicenter Phase II Double-Blind Exploratory Study to Evaluate the Differences Among Various ZDV/ddI Regimens on Quantitative Measures of Viral Burden in Relatively Early HIV-1 Infection

Type of treatment:

AZT, ddI: antiretroviral, reverse transcriptase inhibitor

Purpose:

To learn about the effect of various combinations of AZT and ddI on lowering HIV viral burden in patients with more than 550 CD4 cells (T-cells).

About the study:

Patients are assigned by chance to take either AZT + ddI, AZT + placebo, or ddI + placebo, or placebo alone. Neither the patients nor their doctors know which they are taking until the study ends. One-third of the patients assigned to take AZT + ddI placebo will be switched to ddI + AZT placebo after 16 weeks. One-third of the patients assigned to take AZT + ddI placebo will be switched to ddI + AZT after 16 weeks. Patients assigned to take ddI + AZT placebo will be switched to AZT + ddI placebo after 16 weeks. AZT and ddI are taken by mouth. There is a 2 week observation period at the beginning of the study. Patients will receive study drugs for 32 weeks, and there will be a 4-week observation period at the end of the study. Patients are reimbursed $20 per visit.

Required:

- CD4 cell (T-cell) range: at least 550
- HIV positive
- 13 years or older

Not allowed:

- Ever used antiretroviral drugs (AZT, ddI, ddC, d4T, 3TC, etc.)
- Taken systemic immunomodulators (gp120, gp160, IL-2 and interferons) in past 3 months
- Pregnant women
- Ever had peripheral neuropathy
- Ever had pancreatitis

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

12. HIV Infection: AZT, ddI, d4T

Title:

ACTG 290: A Phase II Randomized Study of the Virologic and Immunologic Effects of d4T versus ddI versus Zidovudine plus d4T versus Zidovudine plus ddI in HIV Infected Patients with CD4 Cell Counts Between 300-600/mm3 and greater than 24 Weeks Zidovudine Experience

Type of treatment:

AZT, d4T, ddI: antiretroviral, reverse transcriptase inhibitor

Purpose:

To learn about the effect of taking AZT with ddI or d4T on CD4 count (T-cells) and HIV viral load.

About the study:

Patients will be assigned by chance to receive d4T + AZT, or d4T + placebo, or ddI + AZT, or ddI + placebo. Neither patients nor their doctors will know which they are taking until the study ends. All drugs are taken by mouth. Visits to the clinic are required every 4-8 weeks. The study lasts at least 48 weeks.

Required:

- CD4 cell (T-cell) range: 300 to 600
- 12 years or older
- HIV positive
- Currently taking AZT for at least the past 12 weeks, and for a total of at least 24 weeks

Not allowed:

- Ever taken ddI, ddC or d4T
- AIDS diagnosis
- Ever had pancreatitis
- Ever had peripheral neuropathy
- Pregnant women

Location:

Stanford University Medical Center
Mary Rinki, RN
(415) 723-6231

Kaiser San Francisco - HIV Research
Gretchen Van Raalte, RN, MS
(415) 202-3482
(Kaiser Health Plan members only)

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

13. HIV Infection: IL-2, d4T

Title:

A Phase II Randomized Open Label Pilot Study of High-Dose and Low-Dose Subcutaneous Proleukin (Aldesleukin) Chiron Recombinant Interleukin-2 in HIV Seropositive Patients with CD4 Counts of 300-700 cells/mm3.

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor
Interleukin-2: immune modulator

Purpose:

To learn about the safety and effectiveness of taking the drugs Interleukin-2 (IL-2) and d4T in combination. To learn how well this combination works against HIV.

About the study:

Patients are assigned by chance to receive one of two dosages of IL-2 plus d4T. Patients will know which doses and which treatments they are receiving. D4T is a pill, IL-2 is given as an injection just under the skin. Patients will be taught how to give themselves injections at home. The study lasts about 8 months and requires frequent visits to the clinic.

Required:

- CD4 cell (T-cell) range: 300 to 700
- HIV positive
- At least 18 years old
- Must be able to tolerate d4T before receiving IL-2

Not allowed:

- Pregnant or breastfeeding women,
- Previous treatment with IL-2
- History of AIDS-defining conditions except oral candidiasis or hairy leukoplakia
- Seizure disorder or ypertension requiring drug therapy
- History of psoriasis, Crohn's disease or other autoimmune disease

Location:

UCSF AIDS Program at SFGH/ICTG
Jose Pacheco
(415) 476-9296, ext. 84101

14. HIV Infection: Curdlan Sulfate

Title:

A Phase I/II Pilot Evaluation of 21 Days of Repeated Dose Curdlan Sulfate Bolus Infusion in Patients With HIV Infection, With or Without a Reverse Transcriptase Inhibitor

Type of treatment:

Curdlan Sulfate: Antiretroviral

Purpose:

To find out if curdlan sulfate (CRDS) is a safe and effective treatment for HIV infection. To find out the highest dose of CRDS patients can safely take.

About the study:

This a dose ranging study. This means that the first patients to enroll in the study receive the lowest dose of curdlan sulfate. If there are no bad side effects, the next patients enter the study at a higher dose. This plan is followed until the highest dose is found that does not cause bad side effects, or until the highest dose researchers plan to study has been given. This is an open label study, so everyone knows what dose they are getting. Curdlan sulfate is given by infusion into a vein 30 minutes a day for 21 days. The study lasts about 35 days.

Required:

- CD4 cell (T-cell) range: 500 or below
- HIV positive
- Between 18 to 70 years old

Not allowed:

- Active opportunistic infection or lymphoma
- History of stomach or intestinal bleeding
- Pregnant or breast-feeding women
- Receiving radiation treatments
- Taking steroids or other drugs intended to raise or lower the function of the immune system

Location:

UCSF AIDS Program at SFGH/ICTG
Jose Pacheco
(415) 476-9296, ext. 84101

ViRx, Inc.
Rick Fallis
(415) 353-5623

15. HIV Infection: AZT, 3TC, Indinavir

Title:

A Multicenter, Double-Blind, Randomized, Six-Month Study to Evaluate the Activity and Safety of MK-639 (Indinavir Sulfate), 800 mg q8h Administered in Combination with Zidovudine, 200 mg q8h, and 3TC, 150 mg b.i.d. (MK-639/ZDV/3TC) Versus ZDV/3TC Versus MK-639 Monotherapy for the Treatment of HIV Infection

Type of treatment:

3TC, AZT: antiretroviral, reverse transcriptase inhibitor
Indinavir: antiretroviral, protease inhibitor

Purpose:

To learn how well the drugs and drug combinations work in lowering the amount of HIV in the blood. This trial compares the new drug MK-639 to the combination of AZT and 3TC to the combination of all three drugs.

About the study:

Patients are assigned by chance to receive either MK-639 (protease inhibitor) alone, AZT plus 3TC, or all three drugs in combination. Neither patients nor their doctors know which they are receiving until the study ends. The study lasts six months, and requires three visits in the first month, and then one visit a month.

Required:

- At least 18 years old
- CD4 cell (T-cell) range: below 50
- HIV positive
- Must have taken AZT for at least 6 months (and tolerated it well), and must not have taken 3TC before

Not allowed:

- Pregnant or breastfeeding women
- Ever used a protease inhibitor before
- Use of immune modulating drugs within 30 days of study entry (no GM-CSF, interferon, IL-2, etc.)
- Use of foscarnet or immune suppressive drugs (like corticosteroids) within two weeks of entry
- Acute hepatitis (liver disease)

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 84098

16. HIV Infection: HBY 097, AZT

Title:

A Randomized, Double-Blind, Dose-Escalation Study Evaluating the Safety and Antiretroviral Activity of HBY 097 vs HBY 097 plus AZT in Patients With Asymptomatic or Mildly Symptomatic HIV Infection.

Type of treatment:

AZT, HBY 097: antiretroviral, reverse transcriptase inhibitor

Purpose:

To see how safe and effective different doses of the new drug HBY 097 are when taken alone and in combination with AZT. To see how well HBY 097 is processed by the body.

About the study:

This is a dose-finding study. This means that the first group to enter the study will be given the lowest dose of HBY 097. If there are no bad side effects observed, the next group of patients will enter the study at a higher dose of HBY 097. Patients are assigned by chance to receive one of two treatments; HBY 097 plus AZT placebo or HBY 097 plus AZT. Neither patients nor their doctors will know which treatment is being taken until the study ends. Study visits will be every week for the first 4 weeks; then every other week up to 14 weeks. The study lasts a total of 3 months.

Required:

- CD4 cell (T-cell) range: 200 to 500
- At least 13 years old
- HIV positive
- Never taken antiretroviral drugs before (less than four weeks total of AZT, ddI, ddC, d4T, etc.)
- Few or no symptoms of HIV disease

Not allowed:

- Past or current AIDS-defining diagnosis
- Pregnant or nursing females
- Use of oral contraceptives

Location:

Stanford University Medical Center
Jane Norris, PA
(415) 723-6231

17. HIV Infection: Transfusion

Title:

SPIRAT2: A Pilot Study of HIV Specific CD8+ Cytoxic Lymphocyte (CTL) Therapy in HIV-Infected Patients with CD4 T-Cells of Less Than 350

Type of treatment:

Transfusion

Purpose:

This is a study of a new cell therapy for HIV infection, using a type of white blood cell which fights infections in the body. These infection-fighting white blood cells are called dendritic cells. They will be donated by an HIV-negative sibling (brother or sister), and will be infused (injected) into a vein of the person with HIV. The purpose of the study is to see if infusions of dendritic cells are safe and if they help the immune system fight HIV.

About the study:

Patients will be given infusions of blood cells (similar to a transfusion) from a brother or sister. Several screening visits over a 3 month period are necessary to make sure blood cells from the patient and his or her sibling are compatible. After the screening period patients receive one infusion each month for 3 months. Patients will be required to stay 24 hours in the hospital for each infusion for observation of side effects. Patients will have study visits twice a month and the study lasts 12 months.

Required:

FOR PATIENT:
- CD4 cell (T-cell) range: below 350
- HIV positive
- same cell type as sibling (to be determined by research staff)
- must be taking some type of anti-HIV drug, (such as AZT, ddI, ddC, d4T or 3TC) at a stable dose during the screening and treatment periods of the study
- at least 18 years old

FOR DONOR:
- HIV negative
- able to donate on three occasions
- Hepatitis B & C negative
- weigh more than 110 lbs.
- at least 18 years old

Not allowed:

- active opportunistic infections
- chronic diarrhea
- wasting syndrome
- any malignancy requiring systemic chemotherapy
- any autoimmune disease or significant cardiovascular disease
- history of receiving any HIV vaccine or use of IL-2 in the last 6 months

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

18. HIV Infection: GEM 91

Title:

A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Safety, Pharmacokinetic and Preliminary Antiviral Activity Study of GEM 91 Administered by Continuous Intravenous Infusion in HIV-Positive Adults. (Phase Ib/II).

Type of treatment:

GEM 91: antiretroviral ("antisense")

Purpose:

To learn about the effects of the new drug GEM 91 in people with HIV. To compare the safety of several different doses of GEM 91. To collect short-term information about the antiviral effects of GEM 91.

About the study:

Patients are assigned by chance to receive GEM 91 or placebo. Neither patients nor their doctors know which they are receiving until the study ends. This is also a "dose escalation" or "dose finding" study, which means that the first few people to join will receive the lowest dose of the drug or placebo. If no bad side effects are seen after two weeks of treatment, the next group receives a slightly higher dose and so on until five different doses are tested. GEM 91 is given as an infusion into a vein. The study lasts a total of seven weeks. Because this is a new drug, the study requires very frequent clinic visits; a total of twenty visits, including every day for two weeks in a row, are required

Required:

- CD4 cell (T-cell) range: 100 to 500
- HIV positive, few or no symptoms
- At least 18 years old
- No active AIDS-related illness requiring treatment during the study
- Any drugs affecting the kidney (except Septra/Bactrim) during the study
- Researchers prefer people who do not require other medications during the study. Septra/Bactrim for PCP prevention is allowed, but most other drugs, including antiretrovirals and MAC and fungal infection prevention drugs are not allowed.

Not allowed:

- Pregnant or breastfeeding women
- Active alcohol or substance abuse
- Current infections or cancers requiring treatment

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

19. HIV Infection: AZT, ddI, 3TC, Nevirapine

Title:

A Master Protocol to Evaluate the Safety and Efficacy of Multi-Drug Combination Antiretroviral Therapy for the Treatment of HIV Infection (ICC002)

Type of treatment:

3TC, AZT, ddI, Nevirapine: antiretroviral, reverse transcriptase inhibitor

Purpose:

To learn which combination of treatments is safest and most effective in treating HIV.

About the study:

Patients are assigned by chance to receive one of three combinations: AZT + ddI + nevirapine or AZT + ddI + 3TC or AZT + ddI + placebo. Neither patients nor their doctors will know which combination they are receiving until the study ends. The study requires monthly visits, and lasts at least one year.

Required:

- CD4 cell (T-cell) range: 200 to 500
- HIV positive
- Never taken any antiretroviral drugs before (no AZT, ddI, d4T, ddC, 3TC)
- At least 13 years old

Not allowed:

- Patients with current drug or alcohol use that might prevent them from following the rules for the study (making appointments and taking all their medications)
- Pregnant or breastfeeding women
- History of acute or chronic pancreatitis

Location:

ViRx, Inc.
Rick Fallis
(415) 353-5623

20. HIV Infection: Vesnarinone, AZT

Title:

A Multicenter, Randomized, Open-Label Phase II Study of Vesnarinone and Zidovudine in Combination and Alone in HIV-infected Persons with CD4+ cell counts less than or equal to 500

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor
Vesnarinone: TNF-alpha (cytokine) inhibitor

Purpose:

To learn more about the safety and anti-HIV effects of AZT, vesnarinone, and AZT and vesnarinone when taken together

About the study:

Patients are assigned by chance to receive either AZT, the new drug vesnarinone, or AZT and vesnarinone together. Patients will know which treatments they are receiving, and both treatments are given as pills. The study

requires weekly clinic visits for six weeks of treatment, and one final followup visit two weeks after completing treatment. Patients are compensated $590 after completing the entire study.

Required:

- CD4 cell (T-cell) range: 500 or below
- HIV positive
- At least 18 years old

Not allowed:

- Any current AIDS-defining opportunistic infections or cancers
- Have haken any antiretroviral therapy (such as AZT, ddI, ddC, d4T, etc.) for more than 4 weeks
- Pregnant women
- History of hart disease or heart abnormalities
- Have been on a clinical trial with vesnarinone

Location:

Camino Medical Group
Sandra Odenheimer, NP
(408) 730-4298

ViRx, Inc.
Rick Fallis
(415) 353-5623

21. HIV Infection: ddI, hydroxyurea

Title:

A Pilot Study to Determine the Effect of Hydroxyurea Alone or in Combination with ddI in HIV Infected Patients

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor
Hydroxyurea: cytotoxic chemotherapy

Purpose:

To find out if hydroxyurea alone or in combination with ddI is safe and effective in reducing the amount of HIV in your blood and to see the effect of these treatments on your CD4 (T-cell) count.

About the study:

Patients take hydroxyurea by itself for the first 12 weeks of the study. During the second 12 weeks, patients will take hydroxyurea in combination with ddI. The study lasts 24 weeks. Ther study requires two 12-hour hospital stays.

Required:

- CD4 cell (T-cell) range: below 400
- HIV positive
- Have never taken ddI before

Not allowed:

- Antiviral therapy in the past 3 months
- History of pancreatitis or alcohol abuse
- Active opportunistic infections
- Pregnant or breast-feeding women

Location:

VA Palo Alto/AIDS Research Center
Larry Mole, PharmD
(415) 493-5000, ext. 64694#

22. HIV Infection: MDL 28, 574 (BuCAST)

Title:

A Randomized, Double-Blind, Active-Controlled, Dose-Ranging Study of the Safety and Efficacy of Chronically Administered MDL 28,574A in the Treatment of Asymptomatic/Mildly Symptomatic HIV-Infected Patients

Type of treatment:

MDL 28,574 (BuCAST): antiretroviral, glycosylation inhibitor

Purpose:

To find out if it is safe to take MDL 28,574A by itself and in combination with AZT. To find the best dose of MDL 28,574A to study in further trials. To learn if MDL 28,574A is helpful in treating HIV disease.

About the study:

There are five groups of patients in this study. Four of the groups are assigned by chance to take one of four different doses of MDL 28,574A or placebo once per day for 12 weeks. After 12 weeks, these four groups take MDL 28,574A or placebo once per day, plus 200 mg. of AZT three times per day for 12 more weeks. The fifth group takes AZT only, at a dose of 200 mg. three times per day for 24 weeks. The study lasts 24 weeks. In addition to the five dose groups outlined above there are two sub-studies, depending on patients' CD4 cell (T-cell) counts: one part of the study is for people with 100 to 300 CD4 cells (T-cells) and one part is for people with 301 to 500 CD4 cells (T-cells).

Required:

- CD4 cell (T-cell) range: 100 to 500
- HIV positive
- Less than six months treatment with AZT or any other anti-HIV drug

Not allowed:

- Active opportunistic infection
- Pregnant or breast-feeding women
- Current or past use of foscarnet
- Anyone who has received any HIV vaccine
- Taking any other experimental drug within 30 days of starting this study
- Chronic diarrhea
- Unexplained fever
- Liver or kidney disease
- Recent alcohol or drug abuse

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 84098

23. HIV Infection: AZT, ddI, Nevirapine

Title:

ACTG 244: A Double-Blinded, Randomized Trial Comparing Zidovudine (ZDV or AZT) vs. ZDV plus Didanosine (ddI) vs. ZDV plus ddI plus Nevirapine in Asymptomatic Patients on ZDV Monotherapy Who Develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA

Type of treatment:

AZT, ddI, Nevirapine: antiretroviral, reverse transcriptase inhibitor

Purpose:

This study is testing a new plan for deciding when to change anti-HIV therapy. This plan looks for a genetic mutation (change) in a certain part of the virus in your body (at codon 215). The researchers believe that when this mutation occurs, an increase in the virus in your body may occur, and your CD4 counts will go down. This study will test to see if that is true, and whether changing anti-HIV drugs at the time of the genetic mutation will slow the virus' growth, and help preserve CD4 levels.

About the study:

All patients are first tested to make sure that they have not already had this genetic mutation to the virus in their body. Those who have not may join the study. At the beginning of the study, all patients take AZT pills plus placebos (pills) for ddI and nevirapine. Patients are seen once a month and their blood is checked for the genetic mutation. If this mutation occurs, patients are assigned by chance to receive AZT alone or AZT plus ddI or AZT plus ddI plus nevirapine. Neither the patients nor their doctors know which drugs they are receiving until the study ends. The study requires visits once a month and lasts four years.

Required:

- CD4 cell (T-cell) range: 300 to 600
- HIV positive
- At least 13 years old
- No symptoms of AIDS
- Must have been taking AZT for at least one month, but less than two years, immediately before starting the study

Not allowed:

- Symptoms of ARC or AIDS
- History of taking any anti-HIV besides AZT (no ddI, ddC, d4T, etc.)
- History of pancreatitis
- Symptoms of peripheral neuropathy
- Currently abusing alcohol or illegal drugs
- Pregnant or breastfeeding women

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

24. HIV Infection: AZT, ddI, Nevirapine, ddC

Title:

ACTG 193A: A Randomized, Double-Blind, Four-Arm Study Comparing Combination Nucleoside, Alternating Nucleoside, and Triple Convergent Therapy for the Treatment of Advanced HIV Disease (CD4 < 50/mm3) in Patients with a Prior History of Nucleoside Monotherapy

Type of treatment:

AZT, ddI, ddC, Nevirapine: antiretroviral, reverse transcriptase inhibitor

Purpose:

To find out which treatment is most helpful for people with low CD4 cell counts.

About the study:

Patients are assigned by chance to one of four groups. The first group takes AZT and ddC. The second group takes AZT and ddI. The third group takes AZT, ddI and nevirapine. The fourth group takes AZT for one month, ddI the next month, then AZT again, and so on until the end of the study. Neither the patients nor their doctors know which drugs are being taken until the study ends. Study visits are once a month.

Required:

- CD4 cell (T-cell) range: 50 or below
- HIV positive
- At least 13 years old

Not allowed:

- Pregnant women
- People currently receiving chemotherapy for cancer (radiation therapy for Kaposi's Sarcoma is ok)
- Current severe peripheral neuropathy (greater than grade 3)
- Currently under acute treatment for an opportunistic infection (within 1 week)
- History of acute or chronic pancreatitis
- Current use of erythromycin, phenytoin, phenobarbital, warfarin, or coumadin
- People who dropped out of the study called ACTG 193

Location:

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

25. HIV Infection: Thymopentin

Title:

Double-Blind Study of Timunox (TP-5, thymopentin) in Asymptomatic HIV-Infected Patients Receiving Antiretroviral Therapy

Type of treatment:

Thymopentin: immune modulator

Purpose:

To learn if the drug thymopentin (also called Timunox or TP-5) is a safe and effective treatment for people who are taking anti-HIV drugs, as well as for people who are not taking these drugs. To find out if thymopentin plus anti-HIV drugs will improve people's health and help them live longer.

About the study:

Patients are assigned by chance to take the drug thymopentin or a placebo. Thymopentin and its placebo are taken by an injection under the skin three times a week. Patients will be taught how to give themselves injections. Neither the patients nor their doctors know which drugs are being taken until the study ends.

Required:

- CD4 cell (T-cell) range: 100 to 400
- HIV positive, with no symptoms
- No history of herpes zoster (shingles) within two years, no oral candidiasis (thrush) in the past year, no history of vaginal candidiasis that did not respond well to treatment, or occurred more than three times a year
- At least 18 years old
- Must have be taking a stable dose of any approved antiretroviral therapy or combination of approved antiretroviral drugs (AZT, ddC, ddI, etc.).
- Able to learn how to give yourself an injection (a shot) under the skin

Not allowed:

- AIDS
- Any experimental drugs, vaccines, or drugs intended to boost the function of the immune system within 30 days
- Anyone who has ever received more than one dose of thymopentin (TP-5) in the past
- Pregnant or breastfeeding
- Peripheral neuropathy due to anti-HIV drugs greater than grade 2

Location:

AIDS Community Research Consortium
Renee Schnell-Smith, RN
(415) 364-6563

26. HIV Infection: AZT, Delavirdine

Title:

M/331/0021: A Double-Blind, Randomized, Dose Response Study of Three Doses of Delavirdine Mesylate (U-90152S) in Combination with Zidovudine (ZDV) versus ZDV alone in HIV-1 Infected Individuals with CD4 Counts of 200 - 500/mm3.

Type of treatment:

AZT, Delavirdine: antiretroviral, reverse transcriptase inhibitor

Purpose:

To find out if the drug delavirdine mesylate combined with AZT is better than AZT alone in treating people with HIV. To learn which dose of U-90 is the most effective and safe. U-90 is a drug that is supposed to work against HIV in a different way than AZT or drugs like it. (It is called a non-nucleoside reverse transcriptase inhibitor, or RTI.)

About the study:

Patients are assigned by chance to receive one of three doses of U-90 pills, or a U-90 placebo pill. Neither the patients nor their doctors know which is being taken until the study ends. Everyone takes real AZT pills. The study lasts for two years, and requires visits every two weeks for the first two months, and every month for the rest of the study. Patients who do not do well on this study after six months may be given a chance to sign up for another study of U-90 with ddI or ddC.

Required:

- CD4 cell (T-cell) range: 200 to 500
- At least 14 years old

Not allowed:

- Taking AZT for more than 6 months,
- Having ever taken anti-HIV drugs that work in a similar way to AZT or U-90, such as ddI, ddC, d4T, 3TC, L-drugs, TIBO, HEPT, atevirdine, APA
- Current substance abuse
- Current clinically significant opportunistic infection, nervous system disorder, or muscle disease
- Women who are pregnant or breastfeeding

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

AIDS Community Research Consortium
Renee Schnell-Smith, RN
(415) 364-6563

Davies Medical Center HIV Institute
Patricia O'Connor, RN
(415) 565-6649

HIVCare, St. Francis Medical Center
Sher Vieira
(415) 353-6215

27. HIV Infection: AZT, ddC, Invirase (Saquinavir)

Title:

A Randomized, Multicenter, Double-blind, Phase III, Parallel Study of Zidovudine (ZDV) Alone Versus ZDV + Zalcitabine (ddC), versus ZDV + Saquinavir (Invirase), versus ZDV + ddC + Saquinavir in Previously Untreated or Minimally Pretreated HIV-Infected Patients with CD4 Lymphocyte Counts from > 50 to < 350 cells/mm3.

Type of treatment:

AZT, ddC: antiretroviral, reverse transcriptase inhibitors
Saquinavir: antiretroviral, protease inhibitor

Purpose:

To find out which drug or combination of drugs is safest and most effective in treating people with CD4 cells between 50 and 350 who have either never taken AZT before, or if they have taken AZT, have taken it for only a short time (less than four months).

About the study:

Patients are assigned by chance to take one of four combinations: the drug AZT alone, the drug Saquinavir plus AZT; AZT plus the drug ddC; or Saquinavir, AZT and ddC all together. All of these drugs and their placebos are in pill form. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts for at least 80 weeks (a year and a half).

Required:

- CD4 cell (T-cell) range: 50 to 350
- HIV positive
- At least 18 years old
- If have taken AZT, have taken it for only four months or less
- Never taken any other anti-HIV drugs (ddI, ddC, d4T, 3TC, etc.)

Location:

Camino Medical Group
Sandra Odenheimer, NP
(408) 730-4298

28. HIV Infection: gp120 Vaccine

Title:

A Phase I, Comparative, Blinded Trial of Several HIV-1 Derived Immunogens in Individuals with Greater than or equal to 500 CD4 cells/mm3.

Type of treatment:

Vaccine, HIV

Purpose:

To compare four experimental HIV vaccines to find out if any one vaccine is more effective than the others. Researchers are trying to figure out which vaccine is the best to test in larger studies.

About the study:

Patients are assigned by chance to receive one of four vaccines or a placebo. Neither patients nor their doctors know which is being given until the study ends. The vaccines and placebo are both given by injection into a muscle. Injections are given monthly for ten months, then once every two months until the study ends. If one of the vaccines is more effective than the others, the researchers may give it to all of the study participants after the study is over.

Required:

- CD4 cell (T-cell) range: above 500
- HIV positive
- At least 13 years old

Not allowed:

- Any prior HIV vaccinations
- Any prior anti-HIV drugs (AZT, ddI, ddC)
- Pregnant or nursing women

Location:

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

29. HIV Infection: AZT

Title:

DATRI 012: Evaluation of the Changes in HIV Burden in Peripheral Blood and Lymphoid Tissue Following AZT Treatment in HIV Infected Patients with CD4 Cells Between 100 and 500.

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor

Purpose:

To find out what effect the drug AZT has on the amount of HIV virus in the blood and lymph tissue.

About the study:

All patients will receive AZT for eight weeks. All patients will have two lymph nodes removed ("biopsied") as part of the study, one at the beginning of the study, and one after 8 weeks, when the AZT treatment is finished. Lymph nodes are small glands that are located throughout the body. Lymph node removal is done through minor surgery under local anesthesia in the clinic. Losing two lymph nodes will not cause long-term health problems. Patients will also have several blood tests. The study lasts nine weeks with a final phone call five weeks later. All participants will be paid $500 for completing the study.

Required:

- CD4 cell (T-cell) range: 100 to 500
- HIV positive
- At least two palpable lymph nodes (nodes that researchers can feel while doing a physical exam)

Not allowed:

- Ever taken any antiretroviral drugs (AZT, ddI, ddC, d4T, 3TC) or chemotherapy at any time in the past
- Current AIDS-related opportunistic infection, AIDS dementia, AIDS wasting, or AIDS-related cancer, except for mild Kaposi's sarcoma or candidiasis.

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

VA Palo Alto/AIDS Research Center
Larry Mole, PharmD
(415) 493-5000, ext. 64694#

30. Anal Cancer Prevention: Isotretinoin, alpha interferon

Title:

ACTG 216: Chemoprevention of Anal Neoplasia Arising Secondary to Anogenital Human Papillomavirus Infection in Persons with HIV Infection

Type of treatment:

Alpha Interferon: immune modulator
Isotretinoin: skin cell growth stimulant

Purpose:

To find the largest amount of isotretinoin that can given in combination with interferon alfa-2a without bad side effects. To learn if isotretinoin alone or isotretinoin and interferon alfa-2a together can help stop anal cancer from getting worse or coming back.

About the study:

This is a dose-finding study, also called a dose escalation study. This means that when patients enter the study they receive a low dose of the isotretinoin. If there are no bad side effects after two weeks at that dose, they are then given a higher dose of the drug. This plan is followed until the highest dose has been found that does not cause bad side effects. The patients are then given this highest dose in combination with interferon alfa-2a. Isotretinoin is a pill. Interferon alfa-2a is given by injection under the skin. Patients are taught to give the injections themselves, so they may take the medicine at home. The treatment part of the study lasts 12 weeks, then there is a follow-up period of 36 weeks.

Required:

- CD4 cell (T-cell) range: not specified,
- HIV positive
- Current Grade 1 or treated Grade 2 or 3 anal intraepithelial neoplasia (AIN, a type of anal cancer). As part of the study screening procedure, all participants will have a small tube briefly inserted into their anus to collect some cells for biopsy. These cells are checked to make sure they are of the type that this study seeks to treat.
- At least 18 years old

Not allowed:

- Active opportunistic infection
- Other types of cancers requiring whole-body chemotherapy. Localized injection of chemotherapy into certain types of cancers, such as Kaposi's sarcoma or basal cell carcinoma, is allowed.
- Women who are pregnant or nursing
- Serious heart, liver or kidney disease
- Active substance abuse
- Certain ther drugs or treatments, such as G-CSF, some antibiotics, drugs intended to increase or decrease the function of the immune system, radiation therapy

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 885-7252

New

31. Anogenital Warts Treatment: Cidofovir Gel

Title:

A Phase I/II Study of the Safety and Efficacy of Cidofovir Topical Gel (HPMPC) in the Treatment of Condyloma Acuminatum in Patients with HIV Infection

Type of treatment:

Cidofovir: antiviral

Purpose:

To see if cidofovir topical gel (also known as HPMPC) is safe and effective in treating Condyloma Acuminatum (warts on the anus or genitals) of patients infected with HIV.

About the study:

All patients in this study will apply cidofovir topical gel directly to their wart(s) once daily, five days a week for one to two weeks. A skin biopsy is required for this study. This means a small piece of tissue will be removed from a wart for the purpose of diagnosing Condyloma Acuminatum. The study lasts from four to eight weeks. Patients will be reimbursed $5 for each visit and $30 for completing the study ($100 total).

Required:

- CD4 cell (T-cell) range: at least 100
- HIV positive
- At least 18 years old
- External anal or genital wart(s) that have failed at least one previous treatment

Not allowed:

- Any wart treatment within four weeks of study entry
- Active lesions of genital herpes, or any inflammatory skin condition in the same area as the wart
- Pregnant or breastfeeding women

Location:

SFGH Dermatology
Erika Klemperer, MD
(415) 206-8680

32. Aphthous Ulcer Treatment: Thalidomide

Title:

ACTG 251: Thalidomide for Treatment of Oral and Esophageal Aphthous Ulcers and HIV Viremia in Patients with HIV Infection

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To learn if thalidomide is a safe and effective treatment for aphthous ulcers in the esophagus and to see if it is safe and effective in preventing a recurrence of aphthous ulcers in the mouth. It has already been determined that thalidomide is effective in treating oral aphthous ulcers. To learn about the effects of thalidomide on HIV.

About the study:

Patients with oral ulcers are given open-label (real) thalidomide for 4 weeks or longer if their oral ulcers do not heal in that time. Thalidomide is taken once a day at bedtime. Once oral ulcers are healed, patients will be assigned by chance to receive a lower, less-frequent dose of thalidomide or placebo during a maintenance phase of the study. Those patients with esophageal ulcers will be assigned by chance to receive thalidomide or placebo at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Biopsy-confirmed aphthous ulcers of the mouth or esophagus, which have been present for at least four weeks
- Negative culture of ulcer for herpes

Not allowed:

- Viral or fungal infection in the ulcer
- Women who are pregnant or nursing
- Active opportunistic infection
- Radiation to the head or neck

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

Kaiser San Francisco - HIV Research
Susan Kirk, RN
(415) 202-3484
(Kaiser Health Plan members only)

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

33. Oral Candidiasis: Amphotericin B

Title:

ACTG 295: A Phase II Trial of Amphotericin B Oral Suspension for Fluconazole-Resistant Oral Candidiasis in HIV-Infection Patients.

Type of treatment:

Amphotericin B: antifungal

Purpose:

To learn if amphotericin B mouthwash is a safe and effective treatment for oral candidiasis (thrush).

About the study:

Everyone in this study receives amphotericin B mouthwash for two weeks. Amphotericin B is a "swish and swallow" mouthwash. After two weeks, people whose candidiasis gets better are given a lower "maintenance" dose of amphotericin B. People whose candidiasis does not get better after two weeks are given two more weeks of the higher dose. If that does not help, they are discontinued from treatment. The study lasts at least six months. People who respond well to amphotericin B may be provided an ongoing supply until it is available by prescription or until the last person completes the study.

Required:

- CD4 cell (T-cell) range: not specified,
- HIV positive
- Oral candidiasis confirmed by laboratory tests
- No significant improvement of thrush after previous use of fluconazole at a certain dose. Fluconazole use must have been over 3 months ago.
- At least 13 years old

Not allowed:

- Unable to "swish and swallow"
- Esophageal candidiasis since being treated with fluconazole
- Thrush that is being treated successfully with fluconazole
- Nursing mothers
- Previous treatment with amphotericin B oral solution

Location:

Kaiser San Francisco - HIV Research
Barbara LeMaire, RN, MS
(415) 202-3486
(Kaiser Health Plan members only)

New

34. CMV Disease: Observational Study

Title:

The Natural History of Cytomegalovirus Infection in Immunocompromised Hosts

Type of treatment:

Observational

Purpose:

To identify those patients with HIV who are at high risk for developing CMV disease.

About the study:

This is an observational study and patients will be asked to participate for one year. Blood tests will be drawn every two months during the one year period. It is hoped that new tests will be developed to help researchers identify patients who are at very high risk for developing CMV disease (such as retinitis, colitis, pneumonia, etc.) Individual tests results will not be available to patients during the study. Any patients who have ever or are now taking any medication to prevent CMV disease are not eligible to participate in this study.

Required:

- CD4 cell (T-cell) range: 0 to 50
- HIV positive

Not allowed:

- Past or current medication to prevent CMV disease (such as ganciclovir)

Location:

Kaiser San Francisco (Ophthalmology)
Anna Dowling, RN
(415) 202-3981
(Kaiser Health Plan members only)

35. CMV Treatment: Cidofovir

Title:

A Randomized Pilot Phase II Study of HPMPC versus Deferred Treatment for Symptomatic Persistent CMV in HIV-Infected Patients Without End Organ CMV Disease

Type of treatment:

Cidofovir: antiviral

Purpose:

To find out if Cidofovir (also known as HPMPC) is a safe and effective treatment for CMV infection. To find out if Cidofovir is safe and well-tolerated when given by infusion into a vein

About the study:

Patients are assigned by chance to begin treatment immediately with Cidofovir, given by infusion into a vein once a week, or to wait four weeks to begin treatment with Cidofovir. Patients will know whether they are receiving treatment or not, and will be checked throughout the study to make sure they do not need immediate treatment. Study visits are every two weeks and the study lasts from 7 to 11 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Two CMV-positive blood cultures, more than 7 days apart
- Symptoms of CMV infection (fever, night sweats and fatigue

Not allowed:

- CMV retinitis, gastritis, or CMV involving any other organ

Location:

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 885-4316

36. CMV Retinitis Treatment: Cidofovir

Title:

ACTG 281: Peripheral CMV Retinitis Trial

Type of treatment:

Cidofovir: antiviral

Purpose:

To find out if Cidofovir (also called HPMPC), is safe and effective in treating CMV Retinitis that is not immediately sight-threatening.

About the study:

This study has two parts: Stage 1 and Stage 2. In Stage 1, patients are assigned by chance to receive either immediate treatment with intravenous Cidofovir, or delayed treatment. In Stage 2, patients will be assigned by chance to receive one of two doses of CIDOFOVIR for maintenance treatment or delayed treatment. Patients assigned to delayed treatment in Stage 1 and Stage 2 will receive Cidofovir if their CMV retinitis begins to spread. Cidofovir is given as in infusion into a vein. Patients receiving Cidofovir will have their first two infusions 7 days apart, and then have a maintenance infusion every 14 days. Infusions will be given at the General Clinical Research Center at San Francisco General Hospital. At each visit, patients will have an eye exam and have blood and urine tests performed. The study will last at least 8 months.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Diagnosis of CMV retinitis (not zone 1)

Not allowed:

- Previous or current therapy with ganciclovir, foscarnet, CMV hyperimmune immunoglobulin or other investigational agents with anti-CMV activity

- Patients with retinal detachments
- CMV disease outside the eye
- Pregnant or lactating women

Location:

UCSF AIDS Program at SFGH / ACTG
Mary Payne, RN
(415) 476-9296, ext. 84602

37. CMV Retinitis Treatment: ISIS 2922

Title:

A Randomized Comparison of Immediate versus Delayed Treatment with Intravitreal Injections of ISIS 2922 in Patients with Peripheral Cytomegalovirus (CMV) Retinitis

Type of treatment:

ISIS 2922: antiviral

Purpose:

To find out if a new treatment for CMV retinitis, called ISIS 2922, is safe and effective.

About the study:

Patients are assigned by chance to receive
either immediate treatment with ISIS 2922, or delayed treatment. Patients assigned to delayed treatment will receive ISIS 2922 if their CMV retinitis begins to spread. ISIS 2922 is given by injection into the eye. Injections are given once a week for three weeks, and then once every other week. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Diagnosis of CMV retinitis in one eye, previously untreated
- At least 18 years old

Not allowed:

- Certain eye infections or other diseases of the eye
- Patients with retinal detachments
- Previous treatment for CMV retinitis
- Less than 10,000 platelets
- Pregnant or breastfeeding women

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

38. CMV Retinitis Treatment: ISIS 2922, Ganciclovir

Title:

A Randomized Comparison of Intravitreal ISIS 2922 plus Ganciclovir versus Ganciclovir as Treatment for Patients with Cytomegalovirus (CMV) Retinitis

Type of treatment:

Ganciclovir, IV: antiviral
ISIS 2922: antiviral

Purpose:

To test the safety and effectiveness of a new drug called ISIS 2922 in combination with ganciclovir compared to ganciclovir alone for treatment of CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 plus ganciclovir or ganciclovir alone. ISIS 2922 is given by injection into the eye. Injections of ISIS 2922 are given every week for three weeks and then every other week until the end of the study. Ganciclovir is given by injection into a vein every 12 hours for 14 days. Patients who receive ganciclovir by injection can have a central line placed so they can receive injections at home. A central line is a small tube (catheter) semi-permanently inserted into a vein, often in the upper chest just below the collar bone. It will be removed at the end of the study. Patients taking ganciclovir will be referred to a home health agency so they can receive ganciclovir injections at home. After 14 days, patients will take ganciclovir tablets until the end of the study. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- Diagnosis of CMV which has not improved with other treatments

Not allowed:

- Certain eye infections or other diseases of the eye to be treated
- Patients with retinal detachments
- Prior treatment with ganciclovir implants or treatment with ganciclovir for more than 4 months
- Patients who have had CMV before
- Chronic diarrhea
- Less then 10,000 platelets
- Pregnant or breastfeeding women

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

39. CMV & HIV Infection: BMS-180194

Title:

Pilot Study of the Antiviral Activity of Multiple Doses of Oral BMS-180194 in AIDS Patients with CMV Viruria and Virosemenia (007)

Type of treatment:

BMS-180194: antiviral

Purpose:

To learn about the effects of a new antiviral drug, called BMS-180194, on CMV.

About the study:

All patients will receive BMS-180194. It is taken as a capsule by mouth twice a day. Patients will go to the clinic once a week for four weeks. At each visit, patients will give urine and semen samples and have blood drawn for clinical laboratory tests. A brief physical examination will also be performed. The study lasts 42 days. Patients will be paid $200 for participation in this study.

Required:

- CD4 cell (T-cell) range: below 200
- Men with AIDS
- CMV viruria (CMV in the urine)
- CMV virosemenia (CMV in semen)

Not allowed:

- Antiretroviral therapy within 2 weeks of the study starts or during the study
- Surgery, blood transfusion or erythropoietin within four weeks before starting the study
- Treatment with any drug for CMV disease within four weeks before starting the study
- Ever had pancreatitis
- Current or recent diarrhea
- Involuntary weight loss of more than 10% of body weight in past 2 months
- Serious illness within four weeks before starting the study

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

40. CMV & HIV Infection: BMS-180194

Title:

Multiple Dose Safety, Pharmacokinetic and Antiretroviral Interation Study of Oral BMS-180194 in AIDS Patients (005)

Type of treatment:

BMS-180194: antiviral

Purpose:

To learn about the effects of a new antiviral drug, called BMS-180194, on CMV and HIV and to learn about the effects of taking it together with AZT.

About the study:

All patients will receive BMS-180194. It is taken as a capsule by mouth twice a day. Patients must be willing to take AZT (600 mg/day), and to spend four long days at the hospital. Patients will go to the clinic twice a week for four weeks, and then once a week for two weeks. Patients will have blood drawn for clinical laboratory tests at each visit, and provide urine and semen samples once a week. The study lasts 42 days. Patients are paid $500 for participation in this study.

Required:

- CD4 cell (T-cell) range: below 200
- Men with AIDS
- CMV viruria (CMV in the urine)
- CMV virosemenia (CMV in semen)

Not allowed:

- Antiretroviral therapy within two weeks before the study starts or during the study
- Surgery, blood transfusion or erythropoietin within four weeks before starting the study
- Treatment with any drug for CMV disease within four weeks before starting the study
- Ever had pancreatitis
- Current or recent diarrhea
- Involuntary weight loss of more than 10% of body weight in past 2 months
- Serious illness within four weeks before starting the study

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

41. CMV Retinitis Treatment: Ganciclovir Pills & Implants

Title:

A Randomized, Controlled Study of the Safety and Preventive Efficacy of Oral Ganciclovir When Used in Conjunction with an Intravitreal Ganciclovir Implant in CMV Retinitis

Type of treatment:

Ganciclovir: antiviral

Purpose:

To compare the safety and effectiveness of three different ways to take ganciclovir for treatment of CMV retinitis

About the study:

Patients will be assigned by chance to receive either ganciclovir given by injection into a vein, ganciclovir taken by mouth plus a ganciclovir implant at the back of the eye, or a ganciclovir implant alone. Patients assigned to receive ganciclovir by injection will have a central line placed so they can receive injections at home. A central line is a small tube (catheter) semi-permanently inserted into a vein, often in the upper chest just below the collar bone. It may be left in place several months before it is changed. It is removed at the end of the study. Patients assigned to receive a ganciclovir implant will have the implant

placed in an out-patient surgical procedure which takes about one hour. No hospitalization is required. All patients in the study must return to the clinic for eye exams and blood tests every two weeks during the first 4 months of the study, and then every month until the end of the study. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS
- At least 13 years old
- Diagnosis of CMV retinitis in one eye
- Practicing birth control (both men and women)

Not allowed:

- CMV retinitis in both eyes
- CMV retinitis that has progressed, despite repeated treatments
- Ever taken oral ganciclovir for treatment of CMV
- Taken more than four months of oral ganciclovir for prevention of CMV
- Chronic diarrhea, nausea or stomach pain
- Certain eye infections or other diseases of the eye to be treated
- Patients with retinal detachments
- Less than 25,000 platelets

Location:

Kaiser San Francisco (Ophthalmology)
Anna Dowling, RN
(415) 202-3981
(Kaiser Health Plan members only)

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

42. Rehydration for Those Receiving Foscarnet for CMV

Title:

A Multicenter Study of Oral Versus Intravenous Hydration in AIDS Patients

Type of treatment:

Fluids, Oral and Intravenous

Purpose:

To find out the best way to prevent dehydration in patients receiving Foscarnet for CMV treatment: drinking liquids by mouth, or receiving liquids by infusion into a vein.

About the study:

All patients receive Foscarnet. Patients are assigned by chance to receive either hydration by infusion of liquid into a vein, or drinking the liquid of their choice (except caffeine or alcohol drinks). The study lasts 3 weeks and requires one study visit a week.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS
- Recent diagnosis of CMV disease
- At least 18 years old

Not allowed:

- Pregnant or breastfeeding women,
- Patients with some other disorder that would get in the way of their drinking significant amounts of liquid voluntarily
- Treatment with an investigational drug within 28 days of study entry
- Allergic to foscarnet

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

43. CMV Retinitis Treatment: Cidofovir

Title:

Phase II, Randomized, Double-blind Study of the Safety and Efficacy of Intravitreous Cidofovir (HPMPC) for the Treatment of Relapsing Cytomegalovirus Retinitis in Patients with AIDS

Type of treatment:

Cidofovir: antiviral

Purpose:

To learn which dose of Cidofovir works best in treating CMV retinitis that has not improved after treatment with other medications.

About the study:

Patients are assigned by chance to receive one of three doses of Cidofovir (same as HPMPC). Neither participants nor their doctors will know which dose they are receiving until the study ends. Cidofovir is given every 1 to 2 months through injections into the eye. The study requires visits every 2 weeks.

Required:

- CD4 cell (T-cell) range: not specified,
- HIV positive
- CMV retinitis diagnosed by an ophthalmologist (eye doctor)
- CMV retinitis that has gotten worse while being treated by ganciclovir or foscarnet for at least 4 weeks.
- Healthy liver and kidneys

Not allowed:

- Currently taking other anti-CMV treatments
- Pregnant women
- CMV disease elsewhere in the body that requires treatment
- Certain other eye diseases in the past or present
- Hemophilia
- Ongoing treatment with famiciclovir or acyclovir above certain doses at study entry

- Previous treatment with cidofovir or current ganciclovir implants

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

44. CMV Retinitis Treatment: Monoclonal antibodies

Title:

ACTG 294: A Phase II/III Trial of Human Anti-CMV Monoclonal Antibody MSL 109 (MACRT)

Type of treatment:

Monoclonal antibody:

Purpose:

To find out if it is safe and effective to take Human Anti-CMV Monoclonal Antibody (MSL 109) in combination with other treatments for CMV retinitis

About the study:

Patients are assigned by chance to receive either MSL 109 or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. MSL 109 is given as an infusion into a vein. Patients receive infusions every two weeks, and have blood drawn once a month. The study lasts at least one year.

Required:

- CD4 cell (T-cell) range: not specified
- 13 years or older
- AIDS diagnosis
- CMV retinitis

Not allowed:

- Current treatment with intravenous immune globulin (IVIG), CMV immune globulin (CMVIG), alpha interferon (alpha-IFN), gamma interferon (gamma-IFN), or interleukin-2(IL-2)

Location:

UCSF AIDS Program at SFGH / ACTG
Mary Payne, RN
(415) 476-9296, ext. 84602

New

45. CMV Retinitis Treatment: ISIS 2922

Title:

A Randomized Comparison of Two Dosage Schedules of Intravitreal ISIS 2922 for Patients with Advanced Cytomegalovirus Retinitis

Type of treatment:

ISIS 2922: antiviral

Purpose:

To find a safe and effective dose of the new treatment called "ISIS 2922" for advanced CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 either every other week, or every week for 3 weeks, then every other week until the end of the study. ISIS 2922 is given by injection into the eye. Study visits are every week for the first 3 weeks, then every other week up to 22 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of advanced CMV retinitis in one or both eyes
- At least two previous anti-CMV retinitis therapies
- At least 18 years old

Not allowed:

- Previous ganciclovir implants
- Psuedoretinitis pigmentosa infection
- Syphilis, past or present
- Pregnant or nursing women

Location:

Mt. Zion HIV Clinical Research
Jacob Lalezari, MD
(415) 476-6356

46. Cryptococcal Meningitis Treatment: Fluconazole, Liposomal Amphotericin B

Title:

A Randomized, Double-Blind, Comparative Trial of Two Doses of Ambisome (Liposomal Amphotericin-B) versus Amphotericin B, followed by Fluconazole in the Treatment of Acute Cryptococcal Meningitis in AIDS Patients.

Type of treatment:

Fluconazole, Liposomal Amphotericin B: antifungals

Purpose:

To see if the new formulation (liposomal) of Amphotericin B is safer and more effective than the older version in treating cryptococcal meningitis. To find out which dose of the new formulation is better.

About the study:

This study is testing a new formulation (called "liposomal") of the drug amphotericin B. The liposomal formulation means that the drug is packaged in fat molecules, which makes higher doses easier to tolerate. Fat molecules are also harder for the body to process, so the drug is not passed as quickly as in a non-liposomal version. This study is also a dose finding study, which means that the first group of people to join will receive a smaller dose of liposomal amphotericin B. If this dose is found to be safe, the next group will receive a higher dose. In this study, people are assigned by chance to receive either the new liposomal formulation, or the standard formulation. Neither the patients nor their doctors will know which they are receiving until the

study ends. Those on the standard formulation receive fluconazole for 8 weeks after two weeks of amphotericin B treatment. Amphotericin B is given as an infusion into a vein. Fluconazole is a pill. Samples of cerebrospinal fluid (CSF) will be taken. A tube is inserted between the bones in the spine and the lower back to collect a sample of CSF. The total length of the study is ten weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Acute cryptococcal meningitis
- HIV positive
- Greater than 1 month old

Not allowed:

- Other systemic fungal infection at time of study entry
- Pregnant or nursing women

Location:

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

Kaiser San Francisco - HIV Research
Gretchen Van Raalte, RN, MS
(415) 202-3482
(Kaiser Health Plan members only)

New

47. *Cryptosporidium* Diarrhea Treatment: Bovine Immunoglobulin Concentrate

Title:

A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Phase II Study of the Safety and Efficacy of Bovine Immunoglobulin Concentrate in the Treatment of Diarrhea Associated With *C. parvum* Infection in Adult Patients With AIDS

Type of treatment:

BIC: immune modulator

Purpose:

To learn if Bovine Immunoglobulin Concentrate (an antibody derived from cows) is an effective treatment for *Cryptosporidium* diarrhea.

About the study:

Patients are assigned by chance to receive BIC or placebo for the first four weeks of the study. BIC and its placebo are powders which are mixed with water and swallowed. Neither patients nor their doctors will know which they are receiving until the study ends. After four weeks, patients may receive open-label (real) BIC for an additional 12 weeks. The study lasts 16 weeks and there are six study visits.

Required:

- CD4 cell (T-cell) range: 200 or below
- HIV positive
- At least 18 years of age
- Stool positive for *Cryptosporidium*

Not allowed:

- Women who are pregnant or nursing
- CMV colitis or enteritis
- Microsporidia or other stool pathogens
- Lactose intolerant

Location:

San Francisco General Hospital GI Clinic
Lisa Thurber
(415) 206-4746

48. Cryptococcosis Treatment: Fluconazole, Flucytosine

Title:

The Treatment of Extraneural Cryptococcosis with Fluconazole Plus Flucytosine in AIDS Patients

Type of treatment:

Fluconazole: antifungal
Flucytosine: chemotherapy

Purpose:

To find out how safe and effective fluconazole plus flucytosine are in the treatment of cryptococcal infection of the blood.

About the study:

Everyone on the study takes both fluconazole and flucytosine. Both fluconazole and flucytosine are pills taken by mouth. The study lasts one year and study visits occur once a month.

Required:

- CD4 cell (T-cell) range: not specified
- Positive blood test for cryptococcal antigen
- Laboratory evidence of Cryptococcus

Location:

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 885-4316

New

49. Diarrhea Treatment: Chinese Herbs

Title:

CC 027: A Placebo-Controlled Pilot Study of Chinese Herbs in HIV-Associated *Cryptosporidium*-Negative Diarrhea

Type of treatment:

Chinese Herbs: Chinese Medicine

Purpose:

To see if taking a Chinese herbal medication is safe and effective in reducing the number of stools per day related to HIV-associated *Cryptosporidium*-negative diarrhea.

About the study:

Patients will be assigned by chance to receive Chinese herbal medication or a placebo. Both are in tablet form. Patients will take a minimum of 12 up to a maximum of 20 tablets a day. The study lasts eight weeks. Study visits will be

conducted at baseline, and at weeks 2, 4, and 8 for evaluation of symptoms and side effects. Blood tests will be done at weeks 4 and 8. Stool samples will be collected at the beginning of the study. Patients will be required to keep a daily stool diary.

Required:

- CD4 cell (T-cell) range: not specified
- At least 17 years old
- HIV positive
- Chronic diarrhea defined as three or more loose stools per day for at least 14 days
- Baseline stool sample negative for treatable parasites including *Cryptosporidium*

Not allowed:

- Any hospital admission within a month prior to study entry
- Documented allergies to Chinese herbs
- Stools containing blood which can be seen by the patient
- Fevers above 101F for greater than seven days
- Alternating constipation/diarrhea
- Any history of a *Cryptosporidium*-positive stool

Location:

Community Consortium
Ask your health care provider
(415) 476-9554

50. Diarrhea: Octreotide

Title:

Continuous Subcutaneous Administration of Octreotide for Refractory AIDS-Associated Diarrhea

Type of treatment:

Octreotide: Digestive Hormone

Purpose:

To find out if giving octreotide continuously (all day, instead of a few times a day) is more effective in relieving diarrhea that does not respond to (or comes back after) other treatments.

About the study:

All patients receive the treatments Pancrease MT16 and Octreotide. Pancrease MT16 is an enzyme supplement that will help the body tolerate octreotide better. Everyone must keep a diary of their bowel movements every day of the study. On certain days, you will be asked to weigh your bowel movements with special equipment provided by the study. After one week of taking Pancrease MT16 pills, you will be shown how to give yourself tubcutaneous infusions of octreotide. These are given using a pump and a small tube that is attached to a small needle that is inserted under the skin of your abdomen (stomach area). The dose of octreotide is increased each week for three weeks, for a total of four weeks. Participants are reimbursed $500 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Diarrhea of a certain quantity for at least two weeks in a row
- If diarrhea is due to parasites such as *Cryptosporidium*, *Isospora belli*, or microsporidia, participants must either be on stable treatment, or no treatment at all, and must agree not to change treatment during the study.

Not allowed:

- Diarrhea due to a treatable cause
- Active CMV of the gastrointestinal tract
- History of ulcerative colitis or Crohn's disease
- Gallstone disease
- Pregnant women

Location:

San Francisco General Hospital GI Clinic
Lisa Thurber
(415) 206-4746

New

51. Hepatitis A Prevention: Vaccine

Title:

A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Immunogenicity of HAVRIX in Subjects With HIV Infection

Type of treatment:

HAVRIX: vaccine-hepatitis-A

Purpose:

To see if HAVRIX, a hepatitis A vaccine, is safe and effective in preventing hepatitis A infection in people with HIV.

About the study:

Patients will be assigned by chance to receive vaccine or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. HAVRIX is given twice by injection under the skin. Study visits will occur once a month. Patients will be on this study indefinitely.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive

Not allowed:

- Pregnant or nursing women
- Active HIV-related opportunistic infections
- Chronic diarrhea or wasting syndrome
- Chemotherapy or immune-modulating drugs

Location:

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 885-4316

52. Chronic Viral Hepatitis Treatment: Acupuncture

Title:

HIV/Chronic Viral Hepatitis Acupuncture Research Program

Type of treatment:

Acupuncture: Chinese medicine

Purpose:

To find out if acupuncture is an effective treatment for chronic viral hepatitis.

About the study:

Patients are assigned by chance to receive traditional Chinese acupuncture, traditional Korean acupuncture, or no acupuncture. Patients do not know if they are getting Chinese or Korean acupuncture until the study ends. Patients receive acupunctrue twice a week for four months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of chronic viral hepatitis
- at least 18 years old
- English or Spanish speaking

Not allowed:

- AIDS
- Currently taking other treatment for chronic viral hepatitis

Location:

Quan Yin Healing Arts Center
Abigail Surasky
(415) 861-4964

New

53. Histoplasmosis Treatment: AmBiSome, Amphotericin B

Title:

A Phase IIB Study to Compare the Safety and Efficacy of AmBisome with Conventional Amphotericin B for Induction Therapy of Histoplasmosis in Patients with AIDS

Type of treatment:

Amphotericin B: antifungal
AmBisome: antifungal

Purpose:

To see if the new formulation (liposomal) of Amphotericin B is safer and more effective than the older formulation in treating moderate to severe histoplasmosis. AmBisome is Amphotericin B that has been packaged in fat molecules which makes higher doses easier to tolerate.

About the study:

Patients will be assigned by chance to receive AmBisome or Amphotericin B. Both medications are given as an infusion into a vein. Neither patients nor their doctors will know which they are taking until the study ends. Patients will receive study medication for two weeks. After the two weeks of induction therapy, all patients will then take oral itraconazole daily for ten weeks. The study lasts 12 weeks. Induction therapy can be stopped after a minimum of seven days for those patients who respond well to treatment.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Evidence of disseminated histoplasmosis

Not allowed:

- Known allergy to amphotericin B
- Any other active opportunistic infection
- Pregnant or nursing women

Location:

UCSF AIDS Program at SFGH/ICTG
Lisa Turner, RN
(415) 476-9296, ext. 84101

New

54. HIV Kidney Disease: Prednisone

Title:

ACTG 271: A Randomized, Placebo-Controlled Study of Prednisone Therapy for HIV-Associated Nephropathy or Kidney Disease (HIVAN)

Type of treatment:

Prednisone: Steroid

Purpose:

To see if prednisone changes the course of kidney disease due to HIVAN and to see if it is safe and effective in treating kidney function. The study will also look at the effect of prednisone on CD4 (T-cell) counts and HIV viral load.

About the study:

Patients are assigned by chance to receive prednisone or placebo. Patients will take the study medication for 11 weeks and then be observed for 13 weeks. Neither patients nor their doctors will know which they are taking until the study ends. Patients will be discontinued from the study if their kidney disease requires dialysis. Treatment will be stopped if patients develop a new opportunistic infection or HIV-related cancer. A kidney biopsy is required prior to entering this study and the cost of the biopsy is the patient's responsibility. Study visits will occur every two weeks for the first 6 weeks, then two to four

weeks apart after that. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not specified,
- HIV positive
- At least 18 years of age
- Biopsy-confirmed HIV-associated Kidney disease
- Stable antiretroviral therapy with AZT or in combination with ddI, ddC or d4T that has been continued for at least 4 weeks
- Must be taking medicine to prevent: PCP, MAC if CD4 count <100, and tuberculosis if PPD positive

Not allowed:

- Kidney disease that is due to anything other than HIV
- Any history of: MAC, CMV disease, cryptococcoses, histoplasmosis, coccidiomycosis, Kaposi's sarcoma or non-Hodgkins lymphoma
- Pregnant or nursing women prior to kidney biopsy
- Renal dialysis within 30 days prior to enrollment
- Previous steroid therapy for HIVAN
- Steroid therapy for any reason within 30 days of enrollment

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

55. KS Treatment: LGD 1069

Title:

A Phase I/II Evaluation of Topical LGD1069 in Patients with Cutaneous Kaposi's Sarcoma

Type of treatment:

LGD1069: retinoic acid, anti-KS

Purpose:

To find out if it is safe to put LGD1069 gel on Kaposi's sarcoma lesions. To find out if using LGD1069 gel in this way makes KS lesions get smaller or go away.

About the study:

Two different strengths of LGD1069 gel are tested in this study. Patients rub one or the other on their KS lesions one, two or four times per day for a total of eight weeks. Everyone knows which strength of the drug they are using, and no placebo is used in this study. If the drug is helping, patients may continue to use it after the study ends.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least four Kaposi's sarcoma lesions on the trunk or abdomen
- At least 18 years old
- Cutaneous Biopsy

Not allowed:

- Active opportunistic infections
- Women who are pregnant or nursing
- May not have other treatment for KS within four weeks of starting this study

Location:

HIVCare, St. Francis Medical Center
Sher Vieira
(415) 353-6215

56. KS Treatment: Tretinoin

Title:

A Multicenter, Phase II/III Study of AR-623 (Tretinoin I.V.) in Patients with AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Tretinoin: skin cell growth stimulant

Purpose:

To find out if AR-623 is a safe and effective treatment for Kaposi's sarcoma. To find out the highest dose of AR-623 patients can safely take. To learn how AR-623 is absorbed and processed in the body.

About the study:

This is a dose-finding study. This means that the first patients who join the study are given the lowest dose of AR-623. If there are no bad side effects the next patients enter the study at a higher dose level. This plan is followed until the highest dose is found that does not cause bad side effects. AR-623 is given by infusion into a vein, either once or twice a week. The study lasts 24 to 32 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Kaposi's sarcoma of the skin (diagnosed using a biopsy)
- At least 18 years old

Not allowed:

- Other chemotherapy, immune therapy, hormone therapy or radiation therapy within two weeks of starting the study
- Kaposi's sarcoma of the internal organs which causes pain or other symptoms
- Active opportunistic infection within 3 weeks of starting study (except *candida*)
- Diabetes
- Cancer other than KS
- Women who are pregnant or nursing

Location:

ViRx, Inc.
Rick Fallis
(415) 353-5623

57. KS Treatment: ddI, alpha interferon

Title:

ACTG 206: Open-Label, Phase II Study with Randomization to One of Two Doses of IFNa-2b Combined with ddI Daily

Type of treatment:

Alpha Interferon: immune modulator
ddI: antiretroviral, reverse transcriptase inhibitor

Purpose:

To find out if it is safe for people with Kaposi's sarcoma to take a combination of the drugs alpha interferon and ddI. To find out if taking this combination of drugs is helpful in treating Kaposi's sarcoma. To learn about the effects of this combination of drugs on the immune system.

About the study:

Everyone in this study takes the same dose of ddI twice per day. In addition, patients are assigned by chance to take one of two doses of alpha interferon. No one takes placebo. Alpha interferon is injected under the skin. Patients learn to inject themselves, so they may take the medicine at home. Patients are in the study for an indefinite length of time, depending on response to treatment.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS
- Kaposi's sarcoma of the skin, lymph nodes or roof (hard palate) of the mouth
- At least 12 years old

Not allowed:

- Any opportunistic infection, now or in the past
- Kaposi's sarcoma of the internal organs
- Severe swelling caused by Kaposi's sarcoma
- Treatment with alpha interferon in the past
- Unable to take ddI because of side effects
- Cancer chemotherapy, radiation therapy, or drugs intended to increase or decrease the function of the immune system within 30 days before starting the study

Location:

Kaiser San Francisco - HIV Research
Gretchen Van Raalte, RN, MS
(415) 202-3482
(Kaiser Health Plan members only)

58. KS Treatment: Tin Ethyl Etiopurpurin

Title:

A Phase III Study of Tin Ethyl Etiopurpurin Photodynamic Therapy of AIDS-Related Kaposi's Sarcoma

Type of treatment:

Tin Ethyl Etiopurpurin: anti-KS

Purpose:

To see if Tin Ethyl Etiopurpurin combined with a laser light beam is an effective way to treat KS lesions.

About the study:

All patients receive one injection of Tin Ethyl Etiopurpurin. KS lesions will be treated with a laser light beam. The study lasts for six months and requires five study visits.

Required:

- CD4 cell (T-cell) range: not specified
- Kaposi's Sarcoma of the skin
- At least 18 years old

Not allowed:

- Greater than 50 KS lesions
- Pregnant or nursing women
- Active opportunistic infections
- Known photosensitivity
- History of lupus erythematosus
- Systemic chemotherapy or interferon in the last 30 days

Location:

UCSF/SFGH Dermatology
Pat Brown, RN
(415) 476-9219

59. Pulmonary KS Treatment: DaunoXome

Title:

DaunoXome For The Treatment of KS With Symptomatic Pulmonary Involvement

Type of treatment:

DaunoXome: chemotherapy

Purpose:

To learn if DaunoXome is helpful for treating KS in the lungs.

About the study:

All patients in this study will be given DaunoXome by infusion into a vein once every two weeks. Patients will need to have two bronchoscopies: one before beginning treatment, to make sure they qualify for the study and one at the end of treatment, to find out how well the treatment has worked. A bronchoscopy is an examination of the lung passages, using a tube inserted into the lungs. Patients will be in this study for an indefinite length of time.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Kaposi's sarcoma in the lungs, with symptoms and proven by biopsy

Not allowed:

- any active opportunistic infection within two weeks before starting the study
- any active lung infection
- pregnant or breast-feeding women
- any kind treatment for KS within 2 weeks before starting this study

Location:

HIVCare, St. Francis Medical Center
Sher Vieira
(415) 353-6215

60. KS Treatment: DOX-SL, Bleomycin, Vincristine

Title:

ACTG 286: Comparison Study of Liposomal Doxorubicin With or Without Bleomycin and Vincristine for the Treatment of Advanced AIDS-Associated Kaposi's Sarcoma

Type of treatment:

DOX-SL, Bleomycin, Vincristine: chemotherapy

Purpose:

To find out if liposomal doxorubicin (DOX-SL) is safe and effective for the long-term treatment of advanced KS. To find out if the combination of DOX-SL, bleomycin and vincristine is safe and if it is more effective than DOX-SL by itself.

About the study:

Patients will be assigned by chance to receive DOX-SL only, or a combination of DOX-SL, bleomycin and vincristine. All medications are given by injection into a vein. Everyone will know which medication(s) they are taking. Patients will receive study medication, physical exams and lab tests every 2 weeks. KS lesions will be examined before study medication is given, once a month during treatment, and one month after the last treatment. The study lasts for 25 treatments, or approximately one year.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- more than 25 skin lesions and/or internal KS or extensive oral lesions
- more than 10 lesions if CD4 cell (T-cell) count is less than or equal to 100
- at least 18 years old

Not allowed:

- any anti-KS therapy within 14 days before starting this study
- prior therapy with DOX-SL, vincristine or bleomycin
- active opportunistic infection
- active tuberculosis
- women who are pregnant or breast-feeding
- other cancer (some types of skin cancers are allowed)

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 885-7252

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

61. KS Treatment: Etoposide

Title:

ACTG 269: Phase II Evaluation of Low-Dose Oral Etoposide for the Treatment of Relapsed or Progressed AIDS-Related Kaposi's Sarcoma after Systemic Chemotherapy

Type of treatment:

Etoposide: chemotherapy

Purpose:

To find out if low-dose etoposide is safe and effective in reducing KS lesions for patients previously treated with chemotherapy.

About the study:

This study is for patients whose KS lesions have gotten worse or have come back after prior treatment with some other kind of chemotherapy. Patients will take etoposide daily every other week for a minimum of a month. Etoposide is a pill taken by mouth. The dose may be raised later if participants do not experience bad side effects, and if their lesions get better by partially or completely going away. Both patients and their doctors will know the drug and dosage that is being given. Patients will continue the medication until their lesions are stable or completely go away, or until the disease gets worse.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- at least 12 years old
- biopsy-proven KS with relapse or progression after prior chemotherapy
- more than 15 lesions and/or oral lesions and/or internal KS

Not allowed:

- prior treatment with etoposide
- any anti-KS therapy within 14 days before starting this study
- active opportunistic infection
- women who are pregnant or breast-feeding
- other cancer (some types of skin cancers are allowed)

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

62. KS Treatment: Topotecan

Title:

An Open, Non-Comparative, Phase II Study of Topotecan, Given as a Continuous 21-day Infusion Every 28 Days, to Patients with Kaposi's Sarcoma

Type of treatment:

Topotecan: chemotherapy

Purpose:

To learn whether and how quickly AIDS-related KS gets better with treatment with Topotecan.

About the study:

All patients receive treatment with Topotecan. Topotecan is given as an infusion into a vein, and participants will need to have a "PIC line" inserted. A PIC line is a small tube (catheter) semi-permanently inserted into a vein, often in the upper chest just below the collar bone. Treatments are given through this tube at home every day for 21 days. All participants go through at least two 21 day treatments, given 4 weeks apart. Patients must come to the clinic weekly to get more drug to infuse at home.

Required:

- CD4 cell (T-cell) range: above 50
- HIV positive
- At least 18 years old
- KS that got worse after treatment with at least 2 different kinds of chemotherapy
- At least 3-5 KS lesions that can be measured

Not allowed:

- More than 2 prior chemotherapy regimens
- KS that has spread to the lungs
- Extensive radiation within last 2 weeks
- Serious opportunistic infection requiring acute therapy (long term MAC treatment is allowed)
- Pregnant or breastfeeding women

Location:

UCSF AIDS Program at SFGH/ICTG
Jose Pacheco
(415) 476-9296, ext. 84101

63. Non-Hodgkin's Lymphoma Treatment: MGBG

Title:

Phase II Evaluation of MGBG (NSC 32946) in Non-Hodgkin's Lymphoma in Patients with Acquired Immunodeficiency Syndrome

Type of treatment:

MGBG: chemotherapy

Purpose:

To find out how well MGBG works for treating AIDS-related non-Hodgkin's lymphoma.

About the study:

All patients in this study receive MGBG, given by infusion into a vein. The drug is given on the first day of the study, the eighth day of the study, and then every two weeks until the study ends. The study ends when one of three things happens; the lymphoma gets worse, there are too many side effects, or the treatment is successful and the patient has complete remission (cure) of the lymphoma.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS
- Non-Hodgkin's lymphoma
- Failure to get better with at least one other treatment for non-Hodgkin's lymphoma

Not allowed:

- Most other types of cancers
- Most active bacterial, viral or fungal infections. Most infections that were treated more than two weeks before starting this study are allowed.
- Currently receiving radiation, other chemotherapy or hormonal therapy
- Serious heart or kidney disease

Location:

UCSF AIDS Program at SFGH/ICTG
Jose Pacheco
(415) 476-9296, ext. 84101

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 885-7252

Ivan Silverberg, MD, Private Practice
(415) 861-7530

64. Central Nervous System Non-Hodgkin's Lymphoma: Chemotherapy, Radiation

Title:

ACTG: 252: Phase II Trial of Sequential Chemotherapy and Radiotherapy for AIDS-Related Primary Central Nervous Systme Lymphoma and Laboratory Correlate: Epstein-Barr Virus in Cerebrospinal Fluid in AIDS-Related Primary Central Nervous System Lymphoma

Type of treatment:

Chemotherapy-systemic
Radiation

Purpose:

To find out if treating patients with chemotherapy (drugs to fight cancer), followed by radiation therapy is an effective treatment for primary Central Nervous System lymphoma.

About the study:

Before starting treatment, samples of the cerebrospinal fluid (CSF) and bone marrow will be taken. A tube is inserted between the bones in the spine and the lower back to collect a sample of CSF. Bone marrow is collected by inserting a needle into the hip bone. On the first day, patients will be given chemotherapy

(cyclophosphamide, doxorubicin, vincristine and dexamethasone). These drugs are injected into a vein. After the first day, patients will take dexamethasone by mouth every day. Patients will also take G-CSF for 10 days. G-CSF is given by injection just under the skin. Patients will be taught how to give themselves injections at home. After patients stop chemotherapy, they will receive radiation therapy to the brain. Radiation therapy will be given 5 days a week for 4 weeks. Patients will come to the clinic once a week to have blood drawn. The study lasts about one month.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- 16 years or older
- CNS non-Hodgkin's lymphoma

Not allowed:

- Ever had chemotherapy (except for Kaposi's sarcoma)
- Ever radiation therapy of the brain
- Pregnant or breastfeeding women
- Current treatment with an investigational drug (except antiretroviral drugs available through a treatment IND)

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

65. Non-Hodgkin's Lymphoma Treatment: Mitoguazone dihydrochlorid

Title:

Phase II Evaluation of Mitoguazone Dihydrochloride in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma Associated with Acquired Human Immunodeficiency Syndrome

Type of treatment:

Mitoguazone dihydrochlorid: Chemotherapy

Purpose:

To find out if the drug mitoguazone dihydrochloride helps people with Non-Hodgkins Lymphoma (NHL) that has gotten worse after treatment with other medications.

About the study:

Everyone receives mitoguazone dihydrochloride, which is given by infusion into a vein. The study may require a lumbar puncture, which is a procedure where a long needle is inserted into the spine and a fluid sample is taken. Study visits are once a week for the first two weeks, and then every other week for 18 more weeks.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS-related NHL
- Failure to get better after treatment with at least one other treatment for NHL

Not allowed:

- Most other cancers, either currently or in the past (KS of the skin, cervical cancer, some skin cancers are allowed)
- Pregnant women
- Serious heart disease

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

66. MAC Prevention: Rifabutin, Ethambutol

Title:

An Open Label Randomized PK/PD Trial of Mycobutin (Rifabutin) Monotherapy, or Rifabutin in Combination with Myambutol (Ethambutol), for Prophylaxis of Mycobacterium-Avium Complex (MAC) Bacteremia in AIDS Patients with CD4 Counts less than $100/mm^3$.

Type of treatment:

Ethambutol, Rifabutin: antimycobacterial

Purpose:

To learn which dose of rifabutin, either alone or combined with ethambutol, produces the highest concentration of drug in the blood. To compare the effects of rifabutin alone to rifabutin plus ethambutol in preventing MAC.

About the study:

Patients are assigned by chance to receive rifabutin alone or rifabutin plus ethambutol. Both patients and their doctors will know which drugs they are receiving. The study requires frequent blood tests at the beginning to determine the best dose(s), and then visits every three months for a year.

Required:

- CD4 cell (T-cell) range: below 100
- HIV positive
- At least 18 years old
- Have had an AIDS-defining disease other than MAC
- Taking medicine to prevent PCP
- No evidence of MAC in blood

Not allowed:

- Pregnant or breastfeeding women
- Have had MAC in the past

Location:

UC Davis Medical Center
Karen Allsup
(916) 734-8282

67. Anemia Treatment for MAC Patients: Erythropoietin

Title:

An Open-Label Treatment Program for Anemia in Patients with AIDS and *Mycobacterium avium* Complex (MAC) Infection Using Recombinant Human Erythropoietin (EPO)

Type of treatment:

Erythropoietin: red blood cell stimulator

Purpose:

To find out if EPO is helpful in treating anemia in people with MAC. To learn if EPO can improve quality of life by decreasing people's fatigue and shortness of breath and improving their ability to perform daily activities.

About the study:

Patients are assigned by chance to one of two treatment arms. One arm receives injections of EPO for 16 weeks, followed by no injections for eight weeks. The second arm receives no injections for eight weeks, followed by injections of EPO for 16 weeks. Injections are given under the skin or into a vein three times per week. The study lasts 24 weeks. Patients who are helped by EPO may qualify to continue taking it after the study ends.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS
- MAC
- EPO blood level less than 500 before starting the study
- 18 to 75 years old
- Either currently taking medication for MAC, or have completed treatment for MAC at least three weeks ago

Not allowed:

- Taking AZT within three weeks before starting the study or during the study
- Known blood disease causing anemia
- Uncontrolled high blood pressure or seizures
- Low iron level in the blood, or other known reasons for anemia

Location:

San Francisco General Hospital/
Ward 86
J.B. Molaghan, NP
(415) 476-4082, ext. 84240

UCSF AIDS Clinic
Cecily Cosby, NP
(415) 476-3226

68. MAC Treatment: Clarithromycin, Ethambutol, Azithromycin

Title:

A Randomized, Double Blind, Comparative Study of Azithromycin vs. Clarithromycin in combination with Ethambutol for the Treatment of Disseminated *Mycobacterium avium* Complex (MAC) Infection in AIDS Patients

Type of treatment:

Azithromycin, Clarithromycin: antibacterials
Ethambutol: antimycobacterial

Purpose:

To compare the safety and effectiveness of two different doses of azithromycin and clarithromycin in combination with ethambutol for treatment of MAC.

About the study:

All patients in this study take ethambutol pills. In addition, patients are assigned by chance to take either azithromycin pills or clarithromycin pills. Neither patients nor their doctors know who is taking azithromycin and who is taking clarithromycin until the study ends. The study lasts six months.

Required:

- CD4 cell (T-cell) range: not specified,
- HIV positive
- At least 13 years old
- Disseminated MAC infection, proven by a blood culture. (Disseminated means that the infection has spread throughout the body)
- No treatment for MAC since the last positive blood culture. Patients who are taking one (and only one) drug to prevent MAC are eligible.

Not allowed:

- Pregnant or nursing women
- Taking any other experimental drug within one week before starting this study

Location:

Summit Medical Center Adult Immunology Clinic
Jamie Carroll, RN
(510) 420-6014, (510) 869-6514

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

AIDS Community Research Consortium
Renee Schnell-Smith, RN
(415) 364-6563

Kaiser San Francisco - HIV Research
Joseph Thatcher, RN, MS
(415) 202-2529
(Kaiser Health Plan members only)

69. MAC Treatment: Rifabutin, Ethambutol, Clofazimine, Clarithromycin

Title:

CPCRA 027: An Open-Label, Randomized Trial of Four Treatment Regimens for Patients with Disseminated *Mycobacterium avium* Complex Disease and Acquired Immunodeficiency Syndrome (AIDS).

Type of treatment:

Clarithromycin: antibacterial
Clofazimine, Ethambutol, Rifabutin: antimycobacterials

Purpose:

To find out if clarithromycin and ethambutol are safe and helpful for the treatment of MAC infection when used in combination with rifabutin or clofazimine. The study will also show which doses of the medications are the best.

About the study:

Everyone in the study takes clarithromycin and ethambutol. In addition, patients are assigned by chance to receive rifabutin or clofazimine. All medications are in pill form. All patients will know which treatment they are taking. The study lasts up to three years.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- MAC disease with symptoms and a positive blood culture
- At least 13 years old

Not allowed:

- Have had any problems taking clarithromycin, ethambutol, rifabutin or clofazimine
- Active tuberculosis

Location:

Community Consortium
Ask your health care provider
(415) 476-9554

70. MAC Treatment: Clarithromycin, Rifabutin, Ethambutol

Title:

ACTG 223: A Phase II/III Prospective, Multicenter, Randomized, Controlled Trial Comparing the Safety and Efficacy of Three Clarithromycin-Containing Combination Drug Regimens for the Treatment of Disseminated *Mycobacterium avium* Complex (MAC) Disease in Persons with AIDS

Type of treatment:

Clarithromycin: antibacterial
Ethambutol, Rifabutin: antimycobacterials

Purpose:

To find out if clarithromycin is safe and helpful for treatment of MAC infection when used in combination with rifabutin and/or ethambutol.

About the study:

Everyone in the study takes clarithromycin. In addition, patients ar assigned by chance to receive rifabutin, ethambutol, or a combination of rifabutin and ethambutol. All patients will know which treatment thay are taking. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- MAC disease with symptoms and a positive blood culture
- Between 18 and 65 years old

Not allowed:

- Current treatment with Seldane or Hismanol
- Current treatment for active infection requiring fluconazole for more than 21 days
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

71. Microsporidiosis Treatment: Albendazole

Title:

A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of Albendazole in the treatment of HIV-Positive Patients With Biopsy-Proven Intestinal Microsporidiosis and Severe Diarrhea

Type of treatment:

Albendazole: antifungal

Purpose:

There is currently no available treatment for HIV diarrhea caused by *Microsporidia*. This study will test how well the drug albendazole works in treating *Microsporidia* in HIV-infected patients twice a day for 28 days. Neither patients nor their doctors will know which treatment is being given for the first 28 days. All patients will then receive real albendazole twice a day 62 days. Patients will be required to keep a diary and give stool specimens for this study.

About the study:

Patients will be assigned by chance to receive 800 mg of albendazole pills or placebo twice a day for 28 days. Neither patients nor their doctors will know which tratment is being given for the first 28 days. All patients will then receive real albendazole twice a day for 62 days. Patients will be requrrred to keep a diary and give stool specimens for this study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive

- Biopsy-proven microsporidiosis within 90 days of study entry
- Diarrhea of a certain quantity for over 14 days prior to study entry

Not allowed:

- Taking any other investigational medication
- Pregnant or nursing mothers

Location:

San Francisco General Hospital GI Clinic
Lisa Thurber
(415) 206-4746

72. Microsporidiosis Treatment: Albendazole

Title:

Efficacy and Tolerability of Albendazole in the Symptomatic Improvement of Diarrhea caused by Microsporidia in HIV-Infected Patients.

Type of treatment:

Albendazole: antifungal

Purpose:

To learn if the drug albendazole is helpful in relieving diarrhea caused by microsporidiosis.

About the study:

All patients receive albendazole pills. There are three visits to the clinic required for a total length of one month.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 13 years old
- Diagnosis of microsporidiosis confirmed by lab tests or biopsy
- Diarrhea of at least 3 liquid bowel movements a day for 30 days just before study entry

Not allowed:

- Pregnant or breastfeeding women

Location:

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 885-4316

New

73. PCP Prevention: TMP/SMX Desensitization

Title:

Trimethoprim Sulfamethoxazole (TMP/SMX) Desensitization Versus Direct Rechallenge in HIV-Infected Patients Who Are at High Risk for PCP and Have Experienced Adverse Reactions to TMP/SMX

Type of treatment:

TMP/SMX: antibacterial

Purpose:

To compare patients who gradually increase their single-strength dose of TMP/SMX (also called Bactrim or Septra) every day for six days to those who start taking the full single-strength dose. To compare the time from starting the medication to the time patients experience a reaction or are diagnosed with PCP.

About the study:

Patients will be assigned by chance to receive either a TMP/SMX liquid or a TMP/SMX tablet. Those patients assigned to a liquid will drink a higher dose each day for six days. They will also take a placebo pill. The other group will receive a TMP/SMX single strength tablet which is taken every day. The second group will also receive a placebo liquid to swallow for six days. Neither patients nor their doctors will know which they are taking for six days. After six days, all patients will be taking real single-strength TMP/SMX pills for six months. There are two study visits; day one and at six months when the study ends. Additional visits may be done in person or by phone.

Required:

- CD4 count (T-cell) range: not specified
- HIV positive
- At least 13 years old
- Have had to stop taking TMP/SMX in the past because of fevers or rash
- Patients must require PCP prophylaxis

Not allowed:

- History of severe adverse reactions to TMP/SMX, such as anaphylaxis, Stevens-Johnson syndrome, mucosal lesions, bronchospasm

Location:

HIVCare, St. Francis Medical Center
Sher Vieira
(415) 353-6215

74. PCP Prevention: Aerosolized Pentamidine

Title:

A Randomized, Double-Blind Trial of 300 mg. once Monthly vs. 600 mg. once monthly of Aerosolized Pentamidine Prophylaxis in Patients at High Risk for Development of *Pneumocystis carinii* Pneumonia (PCP)

Type of treatment:

Pentamidine, aerosolized: antiparasitic (PCP)

Purpose:

To learn which dose of Aerosolized Pentamidine (AP) is safer and more effective in preventing PCP.

About the study:

Patients are assigned by chance to receive one of two doses of AP. Neither patients nor their doctors will know which dose they are getting until the study ends. AP is inhaled (breathed in) through a special device at the research site one time a month. The study lasts one year.

Required:

- CD4 cell (T-cell) range: 200 or below
- At least 18 years old
- Taking an antiretroviral (AZT, ddI, ddC, d4T) at the beginning of the study
- Either never taken AP in the past or have taken 3 doses of 300 mg. AP for 3 months before starting the study.

Not allowed:

- PCP or symptoms of PCP
- Have had PCP more than one time in the past
- Have taken more than 2 months of any other drug (TMP/SMX, dapsone, Fanzidar) for PCP prevention within 3 months of joining the study.
- Asthma requiring daily treatment

Location:

UCSF Infectious Diseases Research
Sheila Duncan, RN
(415) 476-2308

75. PCP Prevention: Atovaquone, Aerosolized Pentamidine

Title:

A Randomized, Open Label Trial of High Dose Atovaquone versus Low Dose Atovaquone versus Aerosolized Pentamidine for Prophylaxis of *Pneumocystis carinii* Pneumonia in Patients with HIV Infection Who are Intolerant of TMP/SMX

Type of treatment:

Atovaquone: antibacterial
Pentamidine, aerosolized: antiparasitic (PCP)

Purpose:

To find out if high dose atovaquone in liquid form is effective in preventing AIDS pneumonia (*Pneumocystis carinii* Pneumonia, or PCP) in patients who cannot take trimethoprim/sulfamethoxazole (also called Septra or Bactrim) and who have had one or more episodes of PCP. To learn about the safety of liquid high dose atovaquone.

About the study:

Patients are assigned by chance to high or low dose atovaquone or aerosolized pentamidine. Atovaquone is taken in liquid form once a day. Aerosolized pentamidine is inhaled into the lungs as a very fine mist, using a device called a nebulizer. It is given once a month. Each treatment takes about 30 minutes. The study lasts 16 months.

Required:

- CD4 cell (T-cell) range: below 200 or, have had PCP before
- HIV positive
- Cannot take Septra or Bactrim because of side effects
- At least 13 years old

Not allowed:

- Taking any other drug which acts against PCP
- Active PCP. If a patient has active PCP, it must be treated before s/he can start the study

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

HIVCare, St. Francis Medical Center
Sher Vieira
(415) 353-6215

Davies Medical Center HIV Institute
Stephanie La Carrubba, RN
(415) 565-6524

76. PCP Prevention: TMP/SMX

Title:

ACTG 268: Gradual Initiation of Trimethoprim/Sulfamethoxazole as Primary *Pneumocystis carinii* Pneumonia (PCP) Prophylaxis

Type of treatment:

Trimethoprim-Sulfamethoxazole: antibacterial

Purpose:

TMP/SMX (also called Septra or Bactrim) is a drug that is often taken to prevent PCP. But some people get allergic side effects such as rash, fever and headaches when they take a whole TMP/SMX pill. The purpose of this study is to find out if taking a very small dose of TMP/SMX at first, and gradually increasing the dose over a two week period, can help people avoid these side effects.

About the study:

Patients are assigned by chance to take one TMP/SMX pill every day or a liquid form of TMP/SMX, which is taken at increasing doses over a two week period. All patients take both a pill and a liquid every day, but only one of these contains the real drug. The other is a placebo. Neither the patients nor their doctors know which is being taken during the first two weeks. At the end of two weeks, all patients take one real TMP/SMX pill every day for ten weeks. The study lasts 12 weeks. Patients who are in this study at the UCSF AIDS Program at SFGH receive $20 per visit to cover travel expenses.

Required:

- CD4 cell (T-cell) range: below 250 or thrush, now or in the past
- HIV positive
- At least 13 years old
- Never had PCP before

Not allowed:

- Already known to be allergic to TMP/SMX or other sulfa drugs
- Have taken TMP/SMX to prevent PCP in the past
- Patients may not start taking antibiotics or anti-HIV drugs within four weeks before starting this study. Patients who began taking these drugs more than four weeks before starting this study may continue to take them.
- Taking antihistamines, steroids or certain other drugs, including glutathione, NAC or leucovorin
- Pregnant women may join the study, but women who are breast-feeding may not join.

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

Stanford University Medical Center
Mary Rinki, RN
(415) 723-6231

77. Peripheral Neuropathy Treatment: Amitriptyline, Mexiletine

Title:

ACTG 242: A Phase II / III Double-Blind Study of Amitriptyline and Mexiletine for Painful Neuropathy in HIV Infection

Type of treatment:

Amitriptyline: antidepressant
Mexiletine: antiarrhythmic, antineuropathy

Purpose:

To find out if amitriptyline or mexiletine can reduce symptoms of painful peripheral neuropathy in people with HIV.

About the study:

Patients are assigned by chance to take amitriptyline, mexiletine or placebo. Neither patients nor their doctors know which is being taken until the study ends. The study lasts ten weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Painful peripheral neuropathy
- At least 18 years old

Not allowed:

- There is a long list of drugs which are not allowed by this study. If you think you may otherwise be eligible, call the study coordinator to find out if you are taking any of these.
- Women who are pregnant or nursing
- Diabetes mellitus
- Certain types of neurological disease
- Heart disease

Location:

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

UCSF AIDS Program at SFGH / ACTG
Mary Payne, RN
(415) 476-9296, ext. 84602

78. Peripheral Neuropathy Treatment: Acupuncture

Title:

CPCRA 022: The Efficacy of a Standardized Acupuncture Regimen Compared with Placebo as a Treatment For Pain Caused by Peripheral Neuropathy in HIV-Infected Patients

Type of treatment:

Acupuncture: Chinese medicine

Purpose:

To find out how effective acupuncture treatments are for pain in the legs and feet caused by peripheral neuropathy.

About the study:

Patients are assigned by chance to receive either acupuncture treatments or "alternate points" acupuncture. "Alternate points" acupuncture involves placing the acupuncture needles in points that are not harmful, but have not been proven to be helpful. Patients do not know which treatment is being given until the study ends. Patients must keep a daily pain diary while in the study. The study lasts 14 weeks. People who complete the study will be given ten free acupuncture treatments.

Required:

- CD4 cell (T-cell) range: not specified
- Painful peripheral neuropathy caused by HIV
- At least 13 years old

Not allowed:

- Active opportunistic infection
- Currently taking anti-depressant drugs, and unwilling to stop for the study.

Location:

Community Consortium
Ask your health care provider
(415) 476-9554

79. PML Treatment: Ara-C

Title:

ACTG 243: A Phase II Multicenter Study Comparing Antiretroviral Therapy Alone to Antiretroviral Therapy Plus Cytosine Arabinoside (Ara-C) For the Treatment of Progressive Multifocal Leukoencephalopathy (PML) in Human Immunodeficiency Virus (HIV) Infected Subjects

Type of treatment:

Ara-C: chemotherapy

Purpose:

To compare the safety and effectiveness of anti-HIV treatment alone (using AZT, ddC or ddI) to a combination of anti-HIV treatment and Ara-C for people with PML. To compare the safety and effectiveness of giving Ara-C by two different methods.

About the study:

All patients in this study must have a brain biopsy to prove that they have PML. Patients are then assigned by chance to one of three treatment arms. The first arm takes only anti-HIV drugs to treat PML. The second arm takes anti-HIV drugs and Ara-C, with the Ara-C given by infusion into a vein. The third arm takes anti-HIV drugs and Ara-C, with the Ara-C given through a device called an Omaya reservoir. The Omaya reservoir slowly releases the Ara-C directly under the covering of the brain, at the base of the skull. One third of the patients in this study will have the Omaya reservoir placed at the base of the skull for infusion of the medicine. This requires a minor operation. The treatment part of the study lasts 26 weeks, with once a month telephone follow-up until the last patient finishes.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- PML
- 18 to 65 years old

Not allowed:

- Taking ganciclovir or foscarnet within 14 days before starting the study
- Taking interferon within 14 days before starting the study
- Taking any anti-HIV drug except AZT, ddC or ddI within 14 days before starting the study
- Taking any experimental treatment for PML within 14 days before starting the study
- Taking Ara-C at any time in the past
- Systemic chemotherapy
- Certain other brain diseases; including cryptococcal meningitis, cytomegaloviral encephalitis, toxoplasmic encephalitis, CNS lymphoma or neurosyphilis
- Women who are pregnant or nursing
- Active opportunistic infection that must be treated while on study

Location:

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

New

80. Prurigo Nodularis: Thalidomide

Title:

Thalidomide for the Treatment of Refractory Prurigo Nodularis and Photodermatitis in Patients With HIV Infection

Type of treatment:

Thalidomide: cytokine inhibitor

Purpose:

To see if thalidomide is safe and effective as a treatment for itchy bumps on the skin associated with HIV infection. These bumps must be diagnosed as "Prurigo Nodularis" and not have responded to any other treatment.

About the study:

Patients are assigned by chance to receive one of two doses of thalidomide. All patients will take real thalidomide. A skin biopsy is required at the beginning and at the end of the study. A skin biopsy is the removal of a small piece of skin. The study lasts one year and study visits are every month. Blood will be drawn every three months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Prurigo nodularis (itchy skin bumps proven by biopsy) that have not gone away with steroid treatment
- 18 years of age or older

Not allowed:

- Pregnant or nursing women
- Moderate-severe peripheral neuropathy
- Currently taking ddC, d4T or systemic chemotherapy

Location:

SFGH Dermatology
Toby Maurer, MD
(415) 206-8680

81. Sinusitis Treatment: Acupuncture, Herbs, Augmentin

Title:

Acupuncture and Herbal Treatment of Chronic HIV Sinusitis

Type of treatment:

Acupuncture, Chinese herbs: Chinese medicine
Augmentin: antibacterial

Purpose:

To find out if traditional Chinese medicine or an antibiotic medicine (Augmentin) is better at reducing symptoms of sinusitis, and at preventing sinusitis from coming back.

About the study:

Patients will be assigned by chance to receive acupuncture and Chinese herbs or Augmentin. The study lasts 12 weeks with 8 weeks of treatment and 4 weeks of no treatment. Study visits will be weekly. Patients will be required to have an examination of their nasal cavity as well as a CAT scan of their nasal passages. These exams will be repeated 30 days after the study ends. Use of any antibiotics other than Septra/Bactrim or use of acupuncture/Chinese herbs during the study is not allowed.

Required:

- CD4 cell (T-cell) range: at least 50
- HIV positive
- History of recurrent sinusitis

Not allowed:

- Active infection with fever over 102
- Any active opportunistic infection
- Pregnancy

Location:

Immune Enhancement Project
Elyse Graham
(415) 252-8711

New

82. TB Prevention: Isoniazid, Rifabutin

Title:

A Phase III Controlled, Double-Blind, Randomized, Multinational Study for the Preventive Therapy of Latent Tuberculosis in HIV-Positive Individuals: Isoniazid (300 mg/d x 12 mos) versus Rifabutin (300 mg/d x 3 mos)

Type of treatment:

Rifabutin, Isoniazid: antimycobacterial

Purpose:

To compare rifabutin and isoniazid to see which is more effective in preventing people with both HIV infection and TB infection from getting active tuberculosis.

About the study:

Patients are assigned by chance to receive either isoniazid daily for one year or rifabutin daily for three months. All patients will take pills (real and placebo) for one year. Neither patients nor their doctors will know which they are receiving. Study visits are once a month for one year.

Required:

- CD4 cell (T-cell) range: unspecified
- HIV positive
- At least 18 years old
- Positive PPD skin test (mantoux method)

Not allowed:

- More than 2 months of any anti-TB drugs after a positive PPD test
- Prior active TB
- Acute hepatitis
- Peripheral neuropathy
- Women who are pregnant or nursing

Location:

San Francisco VA Medical Center
Bill Stanton, RN
(415) 221-4810, ext. 3944

83. TB Prevention, Rifampin, PZA, INH

Title:

ACTG 177: Prophylaxis Against Mycobacterium tuberculosis (MTb) in Patients who are Infected with the Human Immunodeficiency Virus (HIV) and Suspected or Confirmed Latent MTb Infection

Type of treatment:

Rifampin, Pyrizinamide, Isoniazid: antimycobacterial

Purpose:

To learn if taking the drugs rifampin and pyrazinamide (PZA) together, or isoniazid (INH) by itself, can help prevent people with both HIV Infection and TB infection from getting tuberculosis.

About the study:

Patients with a positive skin test for TB, but without symptoms of TB, are assigned by chance to one of two study groups. One group takes rifampin and pyrazinamide pills every day for 60 days. The second group takes INH pills and vitamin B6 every day for one year. Everyone knows which drug(s) they are taking. Patients are studied for up to three years to see if TB develops.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Positive PPD (skin test for tuberculosis)
- At least 13 years old

Not allowed:

- Current active tuberculosis
- Use of other drugs which might prevent or cure tuberculosis
- Active hepatitis or peripheral neuropathy

Location:

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

UCSF AIDS Program at SFGH / ACTG
David Gary, RN
(415) 476-9296, ext. 84095

Kaiser San Francisco - HIV Research
Susan Kirk, RN
(415) 202-3484
(Kaiser Health Plan members only)

84. TB Treatment: Rifapentine, Isoniazid, Rifampin

Title:

Efficacy and Safety of Once-Weekly Rifapentine and Isoniazid Compared to Twice-Weekly Rifampin and Isoniazid in the Continuation Phase of Therapy for Pulmonary Tuberculosis

Type of treatment:

Rifampin, Isoniazid, Rifapentine: antimycobacterial

Purpose:

To compare two different treatment strategies for people with tuberculosis to learn which is easier to follow and more effective in preventing multi-drug resistant tuberculosis.

About the study:

Patients are assigned by chance to receive rifapentine and isoniazid pills once a week or rifampin and isoniazid pills twice a week for six months. Both treatments must be taken in the presence of a study employee, either at the clinic or at patients' homes, this is called "Directly Observed Therapy". The study requires monthly clinic visits for the first four months, then every three months for a year, and then two times in the last year for a total of 2 « years on study. Participants are compensated $20 a week for the first six months and then $10 per visit for the last two years.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive or negative
- Diagnosed with pulmonary TB
- Documented directly observed therapy with a 4-drug combination for 8 weeks
- Fully susceptible to INH and Rifampin
- At least 18 years old

Not allowed:

- Have received more than 70 days of treatment for tuberculosis at study entry
- Pregnant or breastfeeding women
- Other conditions requiring treatment with anti-TB drugs

Location:

San Francisco VA Medical Center
Bill Stanton, RN
(415) 221-4810, ext. 3944

85. HIV Wasting Treatment: Nandrolone Decanoate

Title:

A Randomized, Double-Blind, Placebo-Controlled Study of Nandrolone Decanoate for HIV-Associated Wasting

Type of treatment:

Nandrolone Decanoate: anabolic steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for weight loss in people with HIV.

About the study:

Patients are assigned by chance to receive an injection of nandrolone decanoate or a placebo injection every week for 12 weeks. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all study patients will receive open-label nandrolone decanoate for an additional 12 weeks. Study visits will take place weekly and the study will last 24 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- unintended loss of more than 10% of usual body weight
- normal blood testosterone level
- at least 18 years old

Not allowed:

- active opportunistic infection
- use of other steroids, appetite-stimulating drugs or other drugs intended to treat weight loss, including growth hormone, megace, marinol, thalidomide, etc.
- diarrhea, defined as more than five liquid stools per day
- treatment for cancer other than KS
- women who are pregnant or nursing

Location:

UCSF/SFGH Endocrinology
Kathleen Mulligan, PhD
(415) 206-5882

86. Weight Loss Treatment: Thalidomide

Title:

Phase II, Parallel Group, Placebo Controlled Study of the Safety and Efficacy of Thalidomide in Reducing Weight Loss in Adults with HIV Wasting Syndrome

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To find out if thalidomide is a safe and effective treatment for weight loss in people with AIDS.

About the study:

Patients will be assigned by chance to take one of two doses of thalidomide or a placebo for eight weeks. Neither patients nor their doctors will know which they are taking for these first eight

weeks. After eight weeks, all patients will be offered open-label thalidomide for an additional four weeks. "State-of-the-art" body composition measurements will be taken monthly, as well as CD4 counts and HIV viral load measurements. The study lasts at least 12 weeks. Patients who do not have harmful side effects, and are judged by the researchers to have benefitted from the treatment, are offered continued treatment with Thalidomide after the study ends.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Unintended loss of at least 10% of usual body weight and
- Must not exceed the standard definition of ideal body weight
- Able to eat at least a maintenance diet
- At least 18 years old

Not allowed:

- Women who are pregnant or nursing
- Severe diarrhea (five or more stools per day),
- Peripheral neuropathy (grade 2 or higher)
- Active opportunistic infection
- Cancer other than KS

Location:

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

Kaiser San Francisco - HIV Research
Joseph Thatcher, RN, MS
(415) 202-2529
(Kaiser Health Plan members only)

UCSF/SFGH Endocrinology
Heather Algren
(415) 206-3319

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

87. HIV Weight Loss and Diarrhea Treatment: sole-source diet

Title:

Nutritional and Gastrointestinal Effects of a Sole-Source Diet (Liquid Formula) in AIDS-Related Diarrhea and Weight Loss

Type of treatment:

Sole-source diet

Purpose:

To find out if drinking a sole-source liquid supplement is helpful for patients with HIV who have chronic diarrhea and inability to absorb nutrients from food.

About the study:

Patients will be assigned by chance to continue their regular diet or to receive one of two different liquid supplements. Patients who are assigned to the liquid supplements will take 7 -10 cans a day for ten days. Patients will be required to have two internal exams, one at the first evaluation and one at the final evaluation. These exams (endoscopies) view the inside of the intestinal tract by means of a small flexible tube inserted down the throat. The study lasts approximately 15 days. Patients who complete the study will receive $300 and, if they choose, a six-month supply of the liquid supplement.

Required:

- CD4 cell (T-cell) range: 400 or below
- HIV positive
- Stable medications for at least 60 days
- Stool sample negative for parasites
- Chronic diarrhea; 3-4 or more soft stools per day, 3-7 days a week

Not allowed:

- New (recently diagnosed) opportunistic infections
- No appetite stimulants or hormone therapies for the past two months (except marijuana)

Location:

UCSF/SFGH General Clinical Research Center
Andrew Pelfini
(415) 476-3670

88. HIV Weight Loss in Women: Megace

Title:

A Phase IV Study on the Safety and Efficacy of Megace Oral Suspension in HIV-Positive Females

Type of treatment:

Megace: appetite stimulant

Purpose:

To see if Megace is a safe and effective treatment for loss of appetite and weight loss in women with HIV.

About the study:

Women are assigned by chance to take either 400 mg or 800 mg of Megace Oral Suspension each day. Megace Oral Suspension is a liquid form of Megace which is taken by mouth. Patients will know which dose they are taking. Study visits take place every four weeks and the study lasts six months.

Required:

- CD4 cell (T-cell) range: below 200
- At least 18 years old
- HIV positive women only
- Loss of appetite and unintended loss of more than 10% of normal weight

Not allowed:

- Women who are pregnant or breast-feeding,
- Unable to eat, or unable to digest food properly
- Active, uncontrolled systemic infection (chronic low grade opportunistic infections are acceptable)
- Severe diarrhea, defined as more than five liquid stools per day
- Any hospital admission within two weeks before starting this study

Location:

UC Davis Medical Center
Cindy Wright, PGRII
(916) 734-7004

89. HIV Weight Loss in Women: Megace

Title:

The Nutritional, Metabolic and Body Composition Effects of Megestrol Acetate in Women with AIDS-Related Wasting

Type of treatment:

Megace: appetite stimulant

Purpose:

To learn if taking Megace, a drug that improves the appetite, will have an effect on how much women with HIV-wasting eat, and whether they gain weight or lean body mass.

About the study:

Patients are assigned by chance to receive Megace (a liquid) or placebo. Neither patients nor the doctors know which they are receiving until the study ends. After 12 weeks, every receives Megace for an additional 6 months. The study requires 2 overnight stays at the hospital for special tests. Particpants are paid $300 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- Women with HIV (AIDS o.k., too)
- Age 20 to 60
- Involuntary weight loss of over 5% of ideal body weight

Not allowed:

- Current opportunistic infections
- Use of Megace within 2 months
- Current use of recreational drugs

Location:

SFGH General Clinical Research Center
Ali Strawford
(415) 476-3669

90. HIV Weight Loss in Men: Megace, Testosterone

Title:

Factors Limiting Lean Body Mass Response to Nutrients and Other Anabolic Therapies in AIDS

Type of treatment:

Megace: appetite stimulant
Testosterone: hormone

Purpose:

To see if increasing the amount of food eaten (by using Megace) and improving the body's ability to make new lean tissue (by using Testosterone) has any effect on lean body mass, food intake and metabolism in people with HIV.

About the study:

All particpants receive Megace. In addition, patients are assigned by chance to receive testosterone or placebo. Neither patients nor their doctors will know which they are receiving for the first 12 weeks. Megace is a liquid taken by mouth. Testosterone is taken by injection or by means of a transdermal patch, a thin cloth-like sheet which is worn on the scrotum; it releases testosterone which is absorbed through the skin. A new patch is put on each day. The placebo looks the same and is used in the same way, but it doesn't contain testosterone. After the first 12 weeks, all patients will receive open-label Megace and testosterone 6 months. The study requires two overnight hospital. Participants will be paid $300 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive men only
- Unintended loss of more than 5% of usual body weight
- 20 - 60 years old

Not allowed:

- Taking Megace or testosterone for at least eight weeks before starting this study
- Active opportunistic infections
- Oral lesions which prevent optimal intake or severe diarrhea
- Use of any other steroids or any medications that affect nutrition or metabolism
- Changing antiretroviral therapy during the 30 days before starting this study

Location:

UCSF/SFGH General Clinical Research Center
Andrew Pelfini
(415) 476-3670

91. HIV Weight Loss in Men: Testosterone

Title:

A Placebo-Controlled Evaluation of the Effect of Chronic Testosterone Replacement Therapy (Testodermr Testosterone Transdermal System) on Body Cell Mass and Body Weight in Hypogonadal Males With AIDS

Type of treatment:

Testosterone: hormone

Purpose:

To find out if testosterone replacement can help increase lean body mass, and thereby increase weight, in people with HIV who have experienced an unintended weight loss.

About the study:

Patients will be assigned by chance to use either a testosterone patch or a placebo patch. The testosterone patch is a thin cloth-like sheet worn on the scrotum; it releases testosterone which is absorbed through the skin. A new patch is put on each day, and worn for 22-24 hours. The placebo patch looks the same and is used in the same way, but it does

not contain testosterone. Study visits will take place twice a week for the first month, then once a month for a total of 12 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Men at least 18 years old
- AIDS
- Blood testosterone level below normal
- Documented history of unintended loss of 5% to 20% of usual body weight

Not allowed:

- MAC infection (also called MAI infection)
- Patients requiring chemotherapy or alpha interferon treatment
- Any appetite stimulants or anabolic substances within 21 days before starting this study
- Known allergy to any part of the Testoderm transdermal system (the "patch")

Location:

AIDS Community Research Consortium
Renee Schnell-Smith, RN
(415) 364-6563

Camino Medical Group
Sandra Odenheimer, NP
(408) 730-4298

92. Nutrition in Women with HIV: Observational

Title:

Nutritional Assessment of Women Living with HIV

Type of treatment:

Observational

Purpose:

To learn about the effect of HIV disease on women's body composition (fat, muscle and bone). To learn how HIV disease affects the amount of energy used up by a woman's body when it is at rest. To learn how HIV disease affects women's eating habits. To compare these factors in women and men.

About the study:

This study consists mainly of body measurements and interviews. Every six months, patients come into the clinic for a two-hour study visit. Tests and measurements are done to determine body composition and patients are asked questions about the kind and amount of food they eat. Nutritional counseling is offered to patients who want it. The study lasts for an indefinite length of time. Patients are paid $25 at each visit.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Female

Location:

UCSF/SFGH Endocrinology
Viva Tai, RD, MPH
(415) 206-4090

New

93. Heterosexual HIV Transmission: Educational Interventions

Title:

HIV Prevention Intervention Study with an Embedded Observational Substudy

Type of treatment:

Education, counseling and referrals

Purpose:

To evaluate a behavioral intervention for heterosexual couples, where one member is HIV positive and the other is HIV negative, and to identify biological factors that might be associated with prevention of HIV transmission in women who have been sexually exposed to HIV, but who remain uninfected.

About the study:

The main study is one year long and consists of a brief intensive intervention (one hour per week over four weeks) followed by three 30-minute booster sessions over a period of five months. Couples will be assigned by chance to receive intensive counseling for both partners or intensive counseling for the infected partner, with support and referrals for the negative partner. Participants will be seen at various locations throughout the Bay area. Every 6 months, participants will also be seen for a 2-hour study visit with interviews and lab tests for HIV, STD and pregnancy. *The vaginal mucosal immunity substudy consists of one 15-minute pelvic exam at San Francisco General Hospital. The study lasts three years. Participants are paid for their participation.

Required:

- CD4 cell (T-cell) range: not specified

- HIV positive with a HIV-negative partner of the opposite sex or HIV negative with a HIV-positive patner of the opposite sex
- Sexually active with that partner
- at least 18 years old

Not allowed:

- Unable to speak English or Spanish

Location:

California Heterosexual Partners Study
Cheryl Godwin deMedina
(800) 262-2430

94. HIV Infection and the Central Nervous System: Observational

Title:

HIV Infection & Cognition: Observational

Type of treatment:

Observational:

Purpose:

To learn more about the effects of HIV on the brain and thought processes.

About the study:

Participants are given a series of special examinations including a blood test, neurological examination, cognitive tests, brain wave recordings from metal disks placed on the scalp, and a magnetic resonance imaging (MRI) test. An MRI involves lying on a narrow bed in a recording tube in an MRI machine for about 2 hours. Participants are offered sedatives for this process, but must have an escort to accompany them home if they choose to be sedated. Results of the tests are made available to the participants and their physicians, and participants are paid for their time. Participants may be asked to return every 6-12 months for follow-up tests.

Required:

- CD4 cell (T-cell) range: 200 or below
  or
- HIV negative
  or
- HIV positive with cognitive impairment

Location:

Department of Psychiatry, UCSF / VA
Lynn Nielsen-Bohlman, PhD
(415) 476-7650

95. Pharmacokinetics: INH

Title:

Pharmacokinetics of Antituberculous Agents in HIV

Type of treatment:

Isoniazid: antimycobacterial

Purpose:

To learn how INH is absorbed and processed in the body. To compare the way this happends in men and women, and in people with AIDS and those who do not have HIV Infection.

About the study:

This study is open to men and women with AIDS and men and women who do not have HIV infection. All patients take 300 mg. of INH every day for five days. Blood is drawn to measure the amount of INH in the blood. A small tube is inserted into the lungs to collect fluid and cells in order to measure the amount of INH that is absorbed into the lungs. There are several short study visits and one six-hour study visit. Patients are paid $350 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- AIDS or HIV-negative
- Negative PPD (skin test) for TB, negative chest x-ray for women with HIV

Not allowed:

- Diarrhea, abdominal pain or cramping, nausea, vomiting
- HIV positive, but not meeting the CDC definition for AIDS
- Women who are pregnant or breast-feeding

Location:

UCSF Infectious Diseases Research
Elaine McKenna
(415) 476-2308

96. Pharmacokinetics in Women in Labor: Nevirapine

Title:

ACTG 250: A Phase I Study of Safety and Pharmacokinetics of Nevirapine in HIV-1 Infected Pregnant Women and Neonates Born to HIV-1 Infected Mothers

Type of treatment:

Nevirapine: antiretroviral, reverse transcriptase inhibitor

Purpose:

To find the highest dose of nevirapine which is safe to give to HIV-infected women during labor.

About the study:

This study involves three groups of mothers and their infants. The first group of mothers receives a single dose (100 mg) of nevirapine during active labor (the infant does not receive nevirapine). All mothers and their infants in this study have blood tests for 7 days after the infant is born to watch for side effects. When a safe dose is found, the second group of mothers receives a single dose of nevirapine during labor, and their infant receives a single dose of nevirapine at birth. The third group of mothers receives a single dose of nevirapine during labor and their infants receive multiple doses of nevirapine at birth, if necessary. Nevirapine is taken by

mouth. The study lasts 6 - 8 weeks for mothers, and 6 months for infants.

Required:

- CD4 cell (T-cell) range: not specified
- Mothers must be HIV positive
- Must be at least 34 weeks pregnant

Not allowed:

- Active opportunistic infection or serious bacterial infection
- Intrauterine growth retardation
- Prior treatment with nevirapine
- Anti-HIV therapy other than AZT
- Participation during this pregnancy in a therapeutic or vaccine perinatal trial (ACTG 076, ACTG 233, ACTG 249)

Location:

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

Bay Area Perinatal AIDS Center (BAPAC)
Joel Miller
(415) 206-8919

New

97. Infant Immune Response: Pneumococcal Conjugate Vaccine

Title:

ACTG 292: A Double Blind, Placebo-Controlled Trial of the Safety and Immunogenicity of a Seven Valent Pneumococcal Conjugate Vaccine in Presumed HIV-Infected Infants

Type of treatment:

Pneumococcal vaccine

Purpose:

To learn if infants who receive a pneumococcal conjugate vaccine have more of a reaction at the site of injection and in the body than those who receive placebo. To learn if infants who receive a pneumococcal conjugate vaccine develop more pneumococcal antibody than those receiving placebo.

About the study:

Patients are assigned by chance to receive either pneumococcal conjugate vaccine or placebo. Neither parents nor their doctors will know which they are receiving until the study ends. The study lasts until the infant is 2 years old. There are 10 study visits. Injections will be given at the beginning of the study, 2 months after the study begins, 4 months after the study begins, and at 15 months of age. All infants will receive the licensed pneumococcal polyvalent vaccine at 24 months of age.

Required:

- CD4 cell (T-cell) range: not specified
- Between 56 and 180 days old
- Presumed HIV infection

Not allowed:

- Use of blood products (such as IVIG, VZIG, HbIG, transfusions) within 56 days before joining the study
- Vaccination with pneumococcal vaccine
- Congenital immunoglobulin deficiency, SS or SC hemoglobinopathy, or asplenia
- Use of any immunosuppressant drug (including prednisone) for more than 6 weeks

Location:

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

98. Mother-Newborn Transmission Prevention: HIVIG, IVIG, AZT

Title:

ACTG 185: Phase III Randomized, Double Blind, Controlled Study of the Use of HIVIG for the Prevention of Maternal-Fetal Transmission in Pregnant Women and Newborns Receiving Zidovudine (ZDV).

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor
HIVIG, IVIG: immune modulators

Purpose:

To find out if it is better and safer for HIV+ pregnant women and their infants to take HIVIG and AZT or IVIG and AZT.

About the study:

Patients are assigned by chance to receive IVIG and AZT or HIVIG and AZT. Neither the patients nor their doctors know whether they are taking IVIG or HIVIG until the study ends. The study will last at least two years. IVIG and HIVIG are given by infusion into a vein. AZT is taken by mouth, four times a day. Women will receive infusions of HIVIG or IVIG every month. Infants will receive an infusion only once; at birth, infants will receive AZT by mouth for six weeks. pregnant

Required:

- CD4 cell (T-cell) range: 500 or below
- HIV+ pregnant women
- At least 4 months and less than 7 1/2 months
- Currently taking AZT

Not allowed:

- Ever taken any anti-HIV therapy other than AZT during this pregnancy
- Ever taken IVIG or HIVIG or anti-HIV vaccines during this pregnancy

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

99. HIV Infection in Newborns: Vaccines

Title:

ACTG 230: A Phase I Study to Evaluate the Safety and Immunogenicity of Recombinant HIV-1 Envelope Antigen in Children born to HIV-Infected Mothers.

Type of treatment:

Vaccine, HIV

Purpose:

To find a safe dose in infants of two vaccines (Genentech MN gp120 and Chiron/Biocene rgp 120). To find out which dose and vaccine is most effective.

About the study:

Patients will be assigned by chance to receive one of the vaccines or a placebo. Neither the patients nor their doctor know which is taken until the study ends. The vaccine or placebo is given by injection into a muscle. Patients will have blood tests every month for two years.

Required:

- CD4 cell (T-cell) range: not specified
- Infants less than 72 hours old born to HIV+ women

Not allowed:

- More than 37 weeks gestation
- Infant ever taken other HIV-specific vaccine
- Infant born to mother who has ever taken other HIV-specific vaccine
- Infants being breastfed
- Infants born to women who are positive for Hepatitis B

Location:

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

100. HIV Infection in Children: AZT, ddI,3TC

Title:

ACTG 300: A Randomized, Comparative Study of Zidovudine (ZDV), Lamivudine (3TC) vs. The better of ddI Monotherapy vs. Zidovudine plus ddI in symptomatic HIV-1 Infected Children.

Type of treatment:

3TC, AZT, ddI: antiretroviral, reverse transcriptase inhibitor

Purpose:

To compare the combination of AZT and 3TC to either ddI alone, or ddI + AZT in children with HIV. (There is a another study that compares ddI to AZT + ddI. This study will finish soon, and the findings will be applied to this study).

About the study:

Patients are assigned by chance to receive AZT plus 3TC, or ddI alone, or ddI plus AZT. Neither the patients, their parents, nor the doctors will know which they are receiving until the study ends. All of the medications are given by mouth, either as liquids or pills. The study requires once a month visits, and lasts 2 to 4 years.

Required:

- CD4 cell (T-cell) range: not specified,
- Between 90 days and 15 years old
- For babies under 18 months old, at least 2 positive viral tests
- Some symptoms of HIV-infections or AIDS
- Must not have received more than 56 days of antiretroviral therapy before

Not allowed:

- Currently have cancer
- Pregnant girls

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

101. HIV Infection in Infants: AZT, ddI

Title:

ACTG 239: A Phase I Evaluation of the Safety and Toxicity of Zidovudine and Didanosine in Combination in HIV-Infected or Exposed Infants, and, A Phase II Study of the Effect of Didanosine vs. Combination Therapy with Zidovudine and Didanosine on CD4 Decline and Growth in Infants with HIV Infection

Type of treatment:

AZT, ddI: antiretroviral, reverse transcriptase inhibitor

Purpose:

This is a two-part study. In the first part, researchers are trying to find the best dose of the drug ddI for studies of ddI plus AZT in infants. They will also learn more about the effects of both AZT and ddI on infants' bodies. In the second part of the study, researchers will compare the combination of AZT and ddI to ddI alone to see which is better to fight HIV in infants.

About the study:

The plan for the first part of this study is fairly complicated, and depends on whether the infants have received AZT or not. Please call the contact person below for more details. In the second

part of the study, infants are assigned by chance to receive ddI alone or ddI plus AZT. Neither the parents nor the doctors will know which the infants are receiving until the study ends. The study lasts at least one year. Infants are monitored for physical growth and CD4 counts throughout the study.

Required:

- CD4 cell (T-cell) range: not specified,
- For the first part of the study, infants must be less than 28 days old
- For the second part of the study, infants must be less than or equal to 90 days old
- Must have laboratory tests showing that they have been infected with HIV
- Parent's permission

Not allowed:

- Ever had pancreatitis
- Unstable health at current time

Location:

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

102. HIV Infection in Children and Adolescents: AZT, ddI, Nevirapine

Title:

ACTG 245: A Comparative Study of Combination Antiretroviral Therapy in Children and Adolescents with Advanced HIV Disease.

Type of treatment:

AZT, ddI, Nevirapine: antiretroviral, reverse transcriptase inhibitor

Purpose:

To learn which combination of treatments is better in treating children and adolescents (ages 6 months to 20 years) with HIV.

About the study:

Patients are assigned by chance to receive AZT plus ddI or ddI plus nevirapine or AZT, ddI and nevirapine. Neither the patients, their parents, nor the doctors will know which they are getting until the study ends. All of the study medications are taken by mouth, as pills, tablets, or liquids. The study requires visits to the clinic every month for approximately one year.

Required:

- CD4 cell (T-cell) range: see below,
- Between 6 months and 20 years old
- Laboratory tests showing HIV infection
- Have taken anti-HIV treatments (AZT, ddI, ddC, etc.) for at least 24 weeks total in the past
- Some symptoms of HIV disease progression such as growth failure, at least two AIDS-defining infections, CD4 percent below 15% or confirmed 50% reduction in CD4 percent from previous percent of greater than 19 % within 24 weeks of study entry, or neurodevelopmental / neuropsychological regression.
- Parent's permission, if a minor

Not allowed:

- Current participants on other ACTG studies
- Receiving treatment for cancer
- Pregnant women
- Pancreatitis or Peripheral neuropathy

Location:

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

103. Bacterial Infection Prevention in Children & Adolescents: Antibiotics

Title:

ACTG 254: A Randomized, Phase II/III, Double Blind, Placebo Controlled, Two-armed Study of Micronized-Atovaquone and Azithromycin as Compared to Trimethoprim-Sulfamethoxazole in the Prevention of Serious Bacterial Infections When Used in Children Aged 2-18 Years with HIV Infection.

Type of treatment:

Atovaquone, Azithromycin, Trimethoprim-Sulfamethoxazole: antibacterial

Purpose:

To find out if taking the drugs atovaquone and azithromycin together is as good or better than taking Septra alone in preventing serious bacterial infections.

About the study:

Patients are assigned by chance to receive atovaquone and azithromycin and placebo or Septra and placebo. All drugs are taken by mouth. Neither the patients nor their doctors know which drugs they are taking until the study ends. The study lasts two years.

Required:

- CD4 cell (T-cell) range: not specified
- Between 2 and 18 years old
- HIV positive
- At risk for developing PCP

Not allowed:

- Active PCP
- Past use of atovaquone or azithromycin
- Being treated for MAC, *toxoplasma*, tuberculosis, *cryptosporidia* or *microsporidia*
- Pregnant or breastfeeding

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

104. CMV in Children and Adolescents: Ganciclovir

Title:

ACTG 226: Pharmacokinetic and Tolerance Study of Oral Ganciclovir in HIV-Infected Children with Asymptomatic Cytomegalovirus Infection and Low CD4 Cell Counts or Quiescent Cytomegalovirus Disease.

Type of treatment:

Ganciclovir, oral: antiviral

Purpose:

To find out the best dose of oral ganciclovir for infants, children and adolescents with CMV infection.

About the study:

All patients will receive one treatment of ganciclovir by injection into a vein, and then capsules of ganciclovir to take by mouth every eight hours. Clinic visits are required every other day for the first week, then every two weeks for one month, and then every month until the end of the study (24 weeks total).

Required:

- CD4 cell (T-cell) range: below 150 or
- Stable CMV disease (retinitis, gastrointestinal or congenital)
- HIV positive
- Between 2 weeks and 20 years old
- CMV infection
- Parent or guardian's written consent

Not allowed:

- Loss of sight in one eye for any reason, with CMV retinitis in the other
- Pregnancy
- Acute or chronic diarrhea
- Acute opportunistic infection
- Acyclovir, foscarnet, interferon

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

105. PCP Prevention in Children: Dapsone

Title:

ACTG 179: Comparison of Two Dosage Regimens of Oral Dapsone for Prophylaxis of *Pneumocystis carinii* Pneumonia in Pediatric HIV Infection.

Type of treatment:

Dapsone: antibacterial

Purpose:

To find out if taking dapsone can help prevent PCP in children with HIV who cannot take TMP / SMX (also called Septra or Bactrim). To compare the safety and effectiveness of two different doses of dapsone for preventing PCP. To learn more about how dapsone is absorbed and processed by the body.

About the study:

Patients are assigned by chance to take a low dose of dapsone every day or a higher dose once per week. The drug is taken by mouth. Everyone knows which dose is being taken, and how often. The study lasts at least three months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive children
- Between the ages of one month and 12 years old
- Cannot take Septra/Bactrim because of side effects

Not allowed:

- Taken dapsone in the past
- Severe allergy to sulfa drugs

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

106. PCP Treatment for Children: Atovaquone

Title:

ACTG 227: Phase I Safety and Pharmacokinetics Study of M-Atovaquone (566C80) in HIV Infected Infants and Children

Type of treatment:

Atovaquone: antibacterial

Purpose:

To find out if two doses of a liquid form of atovaquone are safe for infants to take. Atovaquone is a drug used to treat AIDS pneumonia (PCP).

About the study:

Infants between 1 - 3 months old will take 10 mg. of atovaquone each day for 12 days. Infants between 3 months and two years will take 30 mg. of atovaquone each day for 12 days. Atovaquone is a liquid and is taken by mouth.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At risk for AIDS pneumonia (PCP)
- Weighs more than 4 kilograms

Not allowed:

- Active opportunistic infection
- Diarrhea or vomiting
- G6PD deficiency

Location:

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

107. HIV Infection in Children & Adolescents: Observational

Title:

ACTG 219: Pediatrics Late Outcomes

Type of treatment:

Observational

Purpose:

To learn about the long-term survival and quality of life of infants and children enrolled in ACTG studies. To learn more about the differences between HIV disease progression in HIV+ infants and children, and the effects of anti-HIV drugs in children who are not HIV+.

About the study:

All patients get physical exams and blood tests on a regular basis. Information on quality of life is also collected. Patients will be in the study until age 21.

Required:

- CD4 cell (T-cell) range: not specified
- Child of an HIV+ woman who was enrolled in an ACTG study whilepregnant, or
- HIV+ infant or child ever enrolled in an ACTG treatment study

Not allowed:

- Children enrolled only in ACTG 220 or other observational studies

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MS
(510) 428-3885, ext. 2827

UCSF Pediatric Immunology Clinic
Deborah Trevithick, RN, MS
(415) 476-9373

New

108. HIV Infection: VIRACEPT, AZT, 3TC

Title:

A Phase III, Randomized, Double-Blind, Placebo Controlled Study of VIRACEPT in Combination with Zidovudine plus Lamivudine (3TC) versus AZT + 3TC alone in HIV Positive Patients with < 1 Month or No Prior Antiretroviral Treatment.

Type of treatment:

VIRACEPT: antiretroviral, protease inhibitor
AZT (zidovudine, Retrovir), 3TC (lamivudine, Epivir): antiretroviral, protease inhibitor

Purpose:

To learn whether these drugs are safe to take in combination and whether they are effective in lowering the amount of HIV RNA in the blood.

Abouth the study:

Patients are assigned by chance to receive either AZT + 3TC alone, or AZT + 3TC + VIRACEPT. Two thirds of patients receive VIRACEPT. Neither patients nor their doctors will know which they are receiving until the study ends. The study lasts a total of six months, and those who do well on VIRACEPT may be allowed to continue taking it for six more months. Those who do not do well (viral loads or CD4 counts return to their original "baseline" values) may be taken off of the study medications.

Required:

- CD4 cell (T-cell) range: not specified
- HIV RNA: at least 15,000 Eq/mL
- Never taken antiretroviral drugs before (no AZT, ddI, ddC, 3TC) or have taken AZT only for less than one month all together.

Not allowed:

- Active substance users

Location:

Marin Specialty Clinic
Alison Clayton
(415) 499-7377

New

109. Fungal Infection Treatment: Itraconazole desensitization

Title:

Open Label Study of Desensitization to Itraconazole (Sporanox)

Type of treatment:

Itraconazole: antifungal

Purpose:

To learn if those who are hypersensitive to (have allergic reactions to) itraconazole can tolerate the drug without side effects by gradually increasing their dose instead of taking a high dose right away.

About the study:

Patients gradually increase their dose of itraconazole up to the full treatment dose for fungal infections. The study lasts two weeks, with one follow-up visit after three months.

Required:

- CD4 cell (T-cell) range: 100 to 1500
- Documented hypersensitivity (rash, fever, itching, flu-like symptoms, respiratory complications) to itraconazole (Sporanox).
- Between 18 and 75 years old

Location:

Conant Medical Group
Greg Doherty
(415) 661-2613

Compassionate Use, Expanded Access and Treatment IND Programs

Any new drug must be approved by the Food and Drug Administration (FDA) before it can be prescribed by a physician. FDA approval is based on the results of clinical trials. Many months or even years of clinical trials and analysis of the results may be needed before approval can be granted. Such a long testing period is necessary in order to learn about the safety and effectiveness of the drug. But sometimes, even during fairly early phases of testing, a drug may appear to have benefits which outweigh the risks of taking it before it has been fully tested. This is especially true when people cannot take any of the approved drugs, when approved drugs do not work, or for conditions which have previously been untreatable. Compassionate Use, Expanded Access and Treatment IND are programs which allow patients limited access to promising experimental treatments before they have been given full approval by the FDA. They are developed jointly by the FDA and the pharmaceutical company that makes the drug.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Atovaquone	PCP	Glaxo Wellcome Treatment IND	800-722-9294
Azithromycin (Zithromax)	Toxoplasmosis	Pfizer Compassionate Use Protocol	215-972-0420, x2424
	Cryptosporidiosis	Pfizer Compassionate Use Protocol	215-972-0420, x2424
	Disseminated MAC	Pfizer Compassionate Use Protocol	215-972-0420, x2424
AZT (zidovudine, Retrovir)	Children with Advanced HIV	Glaxo Wellcome Treatment IND	800-722-9294
Cidofovir (HPMPC, Vistide)	CMV disease	Gilead Sciences Treatment IND	415-573-4700
ddC (zalcitabine, HIVID)	HIV Infection	Hoffmann-LaRoche Open Label Program	800-332-2144
Foscarnet (Foscavir)	Unapproved indications only	Astra Pharmaceuticals Compassionate Use Protocol	800-388-4148
Ganciclovir Intravitreal Implants (Vitasert)	Sight-threatening CMV retinitis failed or intolerant to IV GCV/Foscarnet	CHIRON Vision Open Label Study	800-CHIRON-8, #2
Human Growth Hormone rHGH (Serostim)	HIV wasting syndrome	Serono Laboratories Treatment IND program	800-714-AIDS
Liposomal daunorubicin (DaunoXome)	Kaposi's sarcoma - Advanced	Vestar, Inc. Compassionate Use Protocol	800-247-3303
Nitazoxanide (NTZ)	Cryptosporidium	Unimed Pharmaceuticals Compassionate Use Protocol	800-864-6330
Sparfloxacin (Cinarcid)	Multidrug resistant TB	Rhone-Poulenc Rorer Compassionate Use Protocol	610-454-5467
Spiramycin	Chronic diarrhea caused by *Cryptosporidium*	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737

California AIDS Drug Assistance Program

The California AIDS Drug Assistance Program (ADAP) was established to provide drugs to individuals who otherwise could not afford them. Individuals are eligible for ADAP if they (1) have an adjusted gross income below $50,000 per year, (2) have a valid prescription from a California-licensed physician, and (3) the drugs they need are not covered by Medi-Cal or other third-party payer. An individual is subject to a co-payment if his/her annual adjusted gross income is between 400% of poverty level and $50,000. Individuals with an annual gross income below 400% of poverty level receive the drugs free of charge.

For more information about ADAP and referrals to local offices, call the California Office of AIDS at **916-327-6784**. In San Francisco, call the Department of Public Health AIDS Office at **415-554-9000**. Other States have similar programs.

California AIDS Drug Assistance Program - Covered Drugs

Generic Name	Trade Name	Indication	Form
Acyclovir	Zovirax	Herpes simplex, herpes zoster	capsule, tablet, ointment
Alpha interferon	Intron-A, Roferon-A	KS, anogenital neoplasms	injection
Amphotericin B	Fungizone	Fungal infections	vial
Atovaquone	Mepron	PCP	tablet, suspension
Azithromycin	Zithromax	Toxoplasmosis, MAC, crypto	capsule
Bleomycin sulfate	Bleonoxane	KS, lymphoma	injection
Clarithromycin	Biaxin	MAC	tablet
Clindamycin HCL	Cleocin	Toxoplasmosis, PCP	capsule
Clofazimine	Lamprene	MAC	capsule
Clotrimazole	Lotrimin, Maculas	Fungal infections	cream, lotion, troche
Cyclophosphamide	Cytoxan	Lymphoma, cancer	injection, tablet
Dapsone		PCP	tablet
Dexamethasone	Decadron, Hexadrol	Anti-inflammatory	tablet, injection
Didanosine (ddI)	Videx	HIV infection	tablet, powder for solution
Doxorubicin	Adriamycin, Doxorubicin	KS, cancer	injection
Dronabinol	Marinol	HIV-related wasting syndrome	capsule
Epoetin alpha	Epogen, Procrit	AZT-related anemia	injection
Ethambutol	Myambutol	MAC, tuberculosis	tablet
G-CSF	Filgrastim,Neupogen	Neutropenia	vial
Fluconazole	Diflucan	Fungal infections	tablet
Flucytosine	Ancobon	Fungal infections	capsule
Foscarnet	Foscavir	CMV disease	infusion
Ganciclovir	Cytovene	CMV disease	vial, capsule
Itraconazole	Sporanox	Fungal infections	capsule
Ketoconazole	Nizoral	Fungal infections	cream, tablet
Leucovorin calcium	Leucovorin	Anemia	tablet, injection
Megestrol acetate	Megace	HIV-related wasting syndrome	tablet, suspension
Methotrexate	Reumatrex	Cancer, psoriasis	tablet, injection
Nystatin	Mycostatin	Fungal infections	troche, tablet, suspension, ointment
Paromomycin	Humatin	Cryptosporidiosis	capsule
Pentamidine	Nebupent, Pentam	PCP prophylaxis and treatment	aerosol, vial
Prednisone	Deltasone, Prednicen-M, Sterapred	Anti-inflammatory	tablet
Pyrimethamine	Daraprim	Toxoplasmosis	tablet
Rifabutin	Mycobutin	MAC prophylaxis	capsule
Stavudine (d4T)	Zerit	HIV infection	capsule
Sulfadiazine	Microsulfon	Toxoplasmosis, meningitis	tablet
TMP/SMX	Bactrim, Septra	PCP prophylaxis, acute PCP	tablet
Trimethoprim	Trimpex, Proloprim	PCP	tablet
Trimetrexate glucuronate	NeuTrexin	PCP, toxoplasmosis	injection
Vinblastine sulfate	Velban	KS, lymphoma	vial
Vincristine sulfate	Oncovin	KS,lymphoma	injection
Zalcitabine (ddC)	Hivid	HIV infection	tablet
Zidovudine (AZT)	Retrovir	HIV infection	capsule

Patient Assistance Programs

Some pharmaceutical companies have programs that provide free or lower cost medications to patients who could not otherwise pay for them. Each program has specific requirements about who is eligible and what kind of financial help is available. If you need help paying for any of the drugs listed below, talk to your doctor. He or she will need to call the coordinators of the appropriate program(s) and give them information about your financial status and prescription drug needs.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
3TC (Lamivudine, Epivir)	HIV Infection	Glaxo Research Institute Reimbursement Program	800-513-3028 (Physician calls only)
Acyclovir (Zovirax)	Herpes simplex, Herpes zoster	Glaxo-Wellcome Co. HIV Patient Assistance Program	800-722-9294
Alpha Interferon-2A recombinant (Roferon-A)	Kaposi's Sarcoma (>200 T-cells) anogenital neoplasms	Hoffmann-LaRoche, Inc. Oncoline (Reimbursement assistance and literature search) Indigent Patient Program	800-443-6676 800-526-6367
Alpha Interferon-2B recombinant (Intron A)	Kaposi's Sarcoma anogenital neoplasms	Schering-Plough Corp. Commitment to Care	800-521-7157
Amphotericin B Lipid Complex (ABLC)	Life threatening fungal infections	Liposome Co. Patient Assistance Program	800-422-5279
Atovaquone (Mepron)	PCP treatment	Glaxo-Wellcome Co. HIV Patient Assistance Program	800-722-9294
AZT (zidovudine) (Retrovir)	HIV infection	Glaxo-Wellcome Co. HIV Patient Assistance Program	800-722-9294
Cimetidine (Tagamet)	Ulcers	SmithKline Beecham, Access To Care	800-546-0420
Ciprofloxacin (Cipro)	Bacterial Infections	Miles Pharmaceuticals Indigent Patient Program	800-998-9180
Clarithromycin (Biaxin)	MAC	Abbot Laboratories Physician calls only	800-688-9118
Clindamycin	PCP treatment	Upjohn Co. Patient Assistance Program-short term financial hardship	800-242-7014
Clofazimine	MAC Treatment/Prevention	Ciba Pharmaceuticals Patient Assistance Program	800-257-3273
Compazine	Nausea	SmithKline Beecham Access To Care	800-546-0420
ddC (zalcitabine, HIVID)	HIV infection	Hoffman-La Roche, Inc. Oncoline	800-443-6676
ddI (didanosine, Videx)	HIV Infection	Bristol Myers Squibb Videx Assistance Program	800-426-7644
d4T (stavudine, Zerit)	HIV Infection	Bristol-Myers Squibb Patient Assistance Program	800-426-7644
DOX-SL (liposomal doxorubicin)	Kaposi's Sarcoma	SEQUUS Pharmaceuticals Patient Assistance Program	800-375-1658
Dronabinol (Marinol)	Wasting	Roxane Laboratories Patient Assistance Program	800-274-8651

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
EPO (erythropoietin) (Procrit)	AZT-related anemia	Ortho Biotech Procrit Financial Assistance Program	800-553-3851
Ethambutol (Myambutol)	TB treatment, MAC treatment	Lederle Laboratories, Patient Assistance Program	800-568-9938
Fluconazole (Diflucan)	Fungal infections	Pfizer Inc. Diflucan patient assistance program	800-869-9979
Foscarnet (Foscavir)	CMV disease, acyclovir-resistant HSV	Astra Pharmaceuticals Foscavir Assistance & Info. on Reimbursement	800-488-3247
Ganciclovir (Cytovene)	CMV disease	Syntex Laboratories Provisional Assistance Programs	800-444-4200
G-CSF (Neupogen)	AZT-related neutropenia	Amgen, Inc.	800-272-9376
GM-CSF (Leukine)	AZT-related neutropenia	Immunex Corporation (Physician calls only)	800-334-6273
Itraconazole (Sporanox)	Histoplasmosis, Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-544-2987
Ketoconazole (Nizoral)	Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-554-2987
Liposomal Daunorubicin (DaunoXome)	Kaposi's sarcoma (advanced)	Vestar, Inc. Limited Patient Assistance Program	800-247-3303 Janet Brennan
Megestrol Acetate (Megace)	HIV-related Wasting	Bristol-Myers Squibb Patient Assistance Program	800-426-7644
Octreotide Acetate (Sandostatin)	Wasting	Sandoz Pharmaceuticals Corp. Indigent Patient Program	800-447-6673
Pentoxifylline (Trental)	HIV Infection Kaposi's Sarcoma, Dementia	Hoechst Roussel Pharmaceuticals Patient Assistant Program	800-422-4779
Pyrimethamine (Daraprim)	Toxoplasmosis	Glaxo-Wellcome Co. HIV Patient Assistance Program	800-722-9294
Saquinavir (Invirase)	HIV Infection	Hoffmann-LaRoches, Inc. Patient Assistance Program	800-282-7780
Streptomycin	TB treatment	Pfizer Inc., Patient Assistant Program	800-254-4445
Trimethoprim - Sulfamethoxazole (TMP-SMX, Septra, Bactrim)	PCP prophylaxis Acute PCP	Glaxo-Wellcome Co. HIV Patient Assistance Program (Septra) Hoffmann-La Roche, Inc. Reimbursement Assistance (Bactrim)	 800-722-9294 800-526-6367
Trimetrexate (Neutrexin)	PCP, Toxoplasmosis	US Bioscience Reimbursement and patient assistance program	800-526-6367, ext. 21 800-887-2467
WinRho SD	HIV-related ITP	Univax Biologics / Physician calls only	800-789-2099

Common Questions about Clinical Trials

What is a clinical trial?

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial.

The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

Why should I join? What do I get out of this?

Here are some of the reasons to join a clinical trial:

- The treatment being tested may work for you.
- Clinical trials may be the only way to get a promising new drug.
- Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available on the "under ground," or by prescription, you may not be able to afford it).
- You can help speed the development of new treatments for HIV.

Will I be used as a "guinea pig"?

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time.

In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that it may prevent you from getting sick.

What if the drug makes me sicker?

The researchers who design the trials always plan for what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

Will I have to take a placebo ("sugar pill")?

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled"study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug or would have happened without treatment.

Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

How can I tell which trial might be good for me?

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

What are my rights as a patient?

The people involved in your care must treat you with consideration and respect. You have the right to:

- be told all the important details about your care
- ask questions and have them answered
- say no to any test, procedure or medication
- go to another health care provider to get more information
- know the names of anyone you talk with
- read your medical records with your health care provider
- make your own decisions about your health care
- know that your medical records will be kept confidential

What are my responsibilities as a patient?

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- be honest about your medical history and anything in your lifestyle which may affect your health
- follow instructions and take the study drug(s) as requested
- keep appointments or re-schedule them in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

What is informed consent?

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving ***informed consent***.

When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

What should I know before I sign the consent form?

Before you sign the consent form, you should know:

- the reasons for using the experimental treatment
- the risks and benefits of taking part in the study
- if there are any extra costs, doctor visits, lab tests, etc.
- what drugs you will have to take

Are there any other questions I should ask before I sign the consent form?

Before you decide to join a trial, you may want to know:

- How will information about me be handled to protect my privacy?
- Can I take the drug after the trial is over? Will I have to pay for it?
- If I get sick or develop health problems while on the trial, will I be taken off the trial?
- How can I find out the results of the trial?
- Are there other studies of this drug I should know about?
- (For women) Do I have to use birth control? If so, what kind? If I become pregnant will I have to leave the study?

What should I do If I don't understand something?

Do not sign the consent form until you understand everything in it. Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions.

Why do some studies pay people to participate?

Some research studies pay people who volunteer to participate in them. Usually, studies only pay when there is no expected medical benefit to participants, such as when a new drug is being tested for only a short amount of time. Sometimes studies pay when they ask a lot of time and energy from participants, such as overnight stays in the hospital, or long surveys about personal issues.

Some researchers feel that the offer of money is not always ethical because it may tempt some people to take risks that they would not take otherwise. Ask and understand why the study is paying participants before you decide whether to join. Keep in mind that studies that pay usually do not pay until the study is over.

When studies do not pay, it is because the potential benefit of the study is felt to be enough compensation for the effort and risk of participating in it. If a study gives you free medication, check-ups, lab tests and helps you to be healthier by curing or preventing disease, then you *do* get something out of your participation.

Getting more information about specific studies

If you want to find out more about a specific clinical trial, call the person listed under "Location" for that trial. This is usually a research nurse or study coordinator. S/he will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

Finding out if you're eligible: The screening visit

If the research nurse thinks you may be eligible, s/he will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

Giving "informed consent"

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join.

The first study visit

After you have signed the consent form, you can join the study during a "baseline" visit, the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

Followup visits

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects you may be having. If everything seems to be all right, you will be asked to come back for regular followup visits. Frequency of visits may vary from daily to every few months, depending upon the study.

Keeping in touch

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

Can women with HIV join clinical trials?

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men.

Women often don't get enough information about clinical trials and think that they cannot join simply because they are women.

Check the index of this Directory for studies that are open only to women, but remember that women may also join nearly all of the other studies listed.

Are there special rules about birth control and pregnancy?

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

What happens if a woman becomes pregnant while in a trial?

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant.

Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion.

If you become pregnant, you may want to talk to the Bay Area Perinatal AIDS Center (BAPAC) at San Francisco General Hospital. They can give you the most current information about pregnancy and HIV disease.

You may call BAPAC at (415) 206-8919.

Treatment-related resources for women with HIV

There is an organization in the Bay Area by and for women with HIV called WORLD (Women Organized to Respond to Life-Threatening Diseases). These women publish a newsletter with treatment information, and organize classes to teach themselves about this HIV, including clinical trials.

You may contact WORLD at (510) 658-6930.

Children and Clinical Trials

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older. Children's research is done by doctors and nurses who are experts in children's bodies and health.

Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in a child. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called ***"informed consent"***.

Where can I find out more about clinical trials for children with HIV?

In the Bay Area, there are several places where you can get information about children with HIV and clinical trials. This directory lists trials for children at the end of the clinical trials section.

Where can children with HIV get health care or join a clinical trial?

Bay Area Perinatal AIDS Center
San Francisco General Hospital
Ms. Joel Miller
(415) 206-8919

Provides medical care for pregnant women with HIV and their unborn children, and for mothers with HIV and their babies.

Children's Hospital of Oakland
Department of Pediatrics
Ann Petru, MD
Jim Riddel, RN
Karen Gold, RN
(510) 428-3336

Conducts clinical trials for children with HIV. Experts in medical care for children with HIV.

Stanford University Medical Center
Department of Pediatrics
Barbara Sullivan, RN
(415) 723-5682

Experts in medical care for children with HIV.

University of California, San Francisco
Department of Pediatric Immunology
Debbie Trevithick, RN, MS
(415) 476-6480

Conducts clinical trials for children with HIV. Experts in medical care for children with HIV. Their Community Advisory Board (CAB) allows people from the community, including parents of children with HIV, to have a say in the research that is done.

What are some other resources for children?

Un Punte Para Ninos (Spanish)
1387 Oak Street
San Francisco, CA 94117
(415) 552-2437

Bridge for Kids (English)
45 Franklin Street, #303
San Francisco, CA 94102
(415) 522-0100

Provides free childcare for children with HIV, and for children whose parents have HIV. English and Spanish speaking.

What does "youth" mean?

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

Why are youth treated differently in clinical trials?

Youth are different physically and emotionally from both children and adults. Healthcare and support programs for youth take these differences into account.

In which trials may youth participate?

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both children's and adults' clinical trials. We list age restrictions for all the trials in this directory.

Do youth under 18 need permission to join a clinical trial?

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial, even if they get medical care at a clinic without permission. There are people working to change the laws in this area, and they may be able to help you join a trial without your parents' permission in certain situations. See the "Common Questions" section of this Directory for an explanation of what it means to give ***"informed consent."***

What services are available for youth with HIV?

Bay Area Young Positives (BAY Positives)
518 Waller Street
San Francisco, CA 94117
(415) 487-1616

BAY Positives is an education, support and advocacy organization by and for young people with HIV from the entire Bay Area.

Project AHEAD
Clark Moore, Acting Director
1242 Market Street
San Francisco, CA 94102
(415) 487-5777

Project Ahead provides information to HIV+ youth and their providers about clinical trials.

Health Initiatives for Youth (HIFY)
Youth Services
Joanne Lothrop, Director
1242 Market Street
San Francisco, CA 94102
(415) 487-5777

HIFY provides programs designed to empower HIV+ youth, including a speakers' bureau, policy and advocacy team, and training and education programs.

Where can I go for health care?

Huckleberry House / Cole Street Clinic
555 Cole Street, #5 (at Haight Street)
(415) 751-8181

Free medical and support services.

Larkin Street Medical Clinic
1044 Larkin Street (at Sutter Street)
(415) 673-0911

Free medical and support services for homeless and runaway youth ages 12 to 23.

UCSF Teen Clinic
400 Parnassus, 2nd Floor, Room A270
(415) 476-8626 (Dave Knopf)

Full medical and support services.

San Francisco General Hospital
1001 Potrero Avenue (between 22nd and 23rd Streets)
Adolescent Clinic (under 18 years old) (415) 206-8376
STAR Services (18 to 21 years old) (415) 206-8436

Free medical and support services.

Kaiser Teenage Clinic
2540 Geary Boulevard, 1st Floor (near Divisidero)
(415) 202-2213

Medical and support services for youth who have Kaiser insurance or MediCal.

Injection Drug Users and Clinical Trials

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory ***do not*** exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial.

Damaged liver or kidneys

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the "screening" visit. If any of the tests are "outside normal limits," you may not be able to join the trial. This is done to protect your health.

Dangerous drug interactions

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know ***every*** drug you are taking, to prevent harmful side effects.

Unable to comply with the "rules" of the study

Some trials have very complicated rules, and some people find it hard to follow them. That is why, if your doctor thinks you are "unreliable," you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.

Injection Drug Users and Clinical Trials

Resources for injection drug and other substance users

San Francisco:

AIDS & Substance Abuse Program (ASAP) (HIV specific) (415) 206-3157
Baker Places (HIV specific) ..... (415) 546-9946
Bayview-Hunter's Point Foundation ..... (415) 822-8200
Operation Concern/18th St. Services (gay & bi men) .. (415) 861-4898
Glide Memorial United Methodist Church ..... (415) 771-6300
Haight-Ashbury Free Clinics ..... (415) 565-1908
Iris Center (women) ..... (415) 864-2364
Ozanam Center (24 hour) ..... (415) 621-6471
Restoration House (African American women) ..... (415) 285-2302
Walden House detox (HIV specific) ..... (415) 241-5574

Alameda County:

Alameda County Drug & Alcohol Services ..... (510) 268-2525
Berkeley - Albany Community Recovery Center ..... (510) 486-8269
East Bay Community Recovery Project ..... (510) 533-0700
14th Street Clinic ..... (510) 533-0800

Clean Needle/Syringe Exchange Programs:

Berkeley
Needle Exchange Emergency Distribution (NEED) no phone
Thurs: 6:00 to 8:00 Hearst at San Pablo

Marin
Needle Exchange Program of Marin (415) 499-6865
call for locations

Oakland
Alameda County Exchange (ACE) (510) 287-8993
Sat: 10:00 to noon Goss between Pine and Cedar
Tues: 7:00 to 9:00 pm East 10th and Derby (East Oakland)

San Francisco
Prevention Point Needle Exchange Program (415) 861-6710
runs eleven exchanges a week, call for times and locations

San Jose
Risk Reduction Task Force (408) 236-2126
Tues/Thurs:6:00 to 7:00 San Pedro, 1/2 block north of Julian
and by appointment

San Mateo County
San Andreas Syringe Exchange (415) 369-0330
Tues: 11:00 to 12:30 Redwood City Train Station (bus turnout)
Tues: 2:00 to 3:00 Value Max parking lot, East Palo Alto
and by appointment

Santa Cruz
Santa Cruz Needle Exchange (408) 427-4557
runs five or six exchanges a week, call for times and locations
and by appointment.

There are also needle and syringe exchange programs in Sonoma County, Mendocino County, Yolo County, Sacramento County, and new programs planned for Chico and Stockton. If you live in one of these areas, call one of the needle/syringe exchange programs listed above for information, they usually know about each other.

American College of Traditional Chinese Medicine
455 Arkansas Street
San Francisco, CA 94107
(415) 282-7600

AIDS Community Research Consortium (ACRC)
1048 El Camino Real, Suite A
Redwood City, CA 94063
(415) 364-6563

ACRC Trials are also available through the San Mateo County AIDS Program, the Santa Clara Valley Medical Center and other participating sites in the South Bay and Santa Cruz. Call ACRC for information about these locations.

Bay Area Perinatal AIDS Center (BAPAC)
San Francisco General Hospital
1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110
(415) 206-8919

Camino Medical Group
582 South Sunnyvale Avenue
Sunnyvale, CA 94086
(408) 730-4298

Children's Hospital of Oakland - HIV Program
747 - 52nd Street
Oakland, CA 94609
(510) 428-3337

Community Consortium
(See page 69 for list of participating sites and providers)
(415) 476-9554

Davies Medical Center - HIV Institute
Castro and Duboce Streets
San Francisco, CA 94114
(415) 565-6058

East Bay AIDS Center
3031 Telegraph Avenue, Suite 235
Berkeley, CA 94705
(510) 204-1870

Highland General Hospital Adult Immunology Clinic
1411 East 31st Street
Oakland, CA 94602
(510) 437-4050

HIVCare, Saint Francis Memorial Hospital
900 Hyde Street
San Francisco, CA 94109
(415) 775-4321

Immune Enhancement Program
3450 16th Street
San Francisco, CA 94114
(415) 252-8711

Kaiser Permanente Medical Center / HIV Research Unit
2590 Geary Boulevard
San Francisco, CA 94115
(415) 202-3480

Marin County Specialty Clinic
250 Bon Air Road
Greenbrae, CA 94904
(415) 499-7377

Mt. Zion Medical Center / HIV Clinical Research Center
1600 Divisidero Street
San Francisco, CA 94115
(415) 476-6356

Quan Yin Healing Arts Center
1748 Market Street
San Francisco, CA 94114
(415) 861-4964

San Francisco General Hospital - GI Clinic
1001 Potrero Avenue, Room 3C
San Francisco, CA 94110
(415) 206-8822

San Francisco General Hospital - Koret Center For Human Nutrition
1001 Potrero Avenue, Building 40, Room 4101
San Francisco, CA 94110
(415) 206-4090

Clinical Trials Sites

San Mateo County AIDS Program
3700 Edison Street
San Mateo, CA 94403
(415) 573-2588

Santa Clara County Health Department
Early Intervention Project
976 Lenzen Avenue
San Jose, CA 95126
(408) 299-6245

Santa Clara Valley Medical Center
AIDS Research Annex, Room 108
751 South Bascom Avenue
San Jose, CA 95128
(408) 885-4316

Ivan Silverberg, MD
45 Castro Street, #225
San Francisco, CA 94114
(415) 861-7530

Stanford University Medical Center
Center for AIDS Research
300 Pasteur Drive, Room S-156
Stanford, CA 94305
(415) 723-6231

Summit Medical Center - Adult Immunology Clinic
3012 Summitt Street, 6th Floor
Oakland, CA 94609
(510) 420-6014 or (510) 869-6514

University of California San Francisco
AIDS Program at San Francisco General Hospital
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
(415) 476-9296

University of California San Francisco - BARCWA
(Bay Area Research Consortium on Women & AIDS)
400 Parnassus Avenue, #AC16
San Francisco, CA 94143
(415) 476-1956

University of California San Francisco - HIV Clinic
400 Parnassus Avenue, Fifth Floor
San Francisco, CA 94143
(415) 476-3226

University of California San Francisco
Infectious Diseases Research
505 Parnassus Avenue, Room AC30B
San Francisco, CA 94143-0919
(415) 476-2308

University of California San Francisco /
Mt. Zion Cancer Center AIDS Oncology Practice
2356 Sutter Street, 5th Floor, Pavilion
San Francisco, CA 94115
(415) 885-7329

University of California San Francisco /
Pediatric HIV Unit
505 Parnassus Avenue, Room M679
San Francisco, CA 94143
(415) 476-9373

Veterans Administration Medical Center, SF
4150 Clement Street
San Francisco, CA 94121
(415) 221-4810, ext. 3763

Veterans Administration Medical Center, SF /
UCSF Department of Psychiatry
4150 Clement Street
San Francisco, CA 94121
(415) 476/7650

Veterans Admin. Palo Alto / AIDS Research Center
801 Miranda Avenue
Palo Alto, CA 94304
(415) 493-5000, extension 4274

ViRx, Inc.
1375 Sutter Street, Suite 407
San Francisco, CA 94109
(415) 353-5623

Community Consortium Sites and Providers

The Community Consortium conducts clinical trials at over a dozen sites in the San Francisco Bay Area. Health care providers who are participating in the Consortium's clinical trials program are listed below. If you are interested in enrolling in a Consortium clinical trial and your health care provideris listed here, you can discuss enrollment during your next office visit.

San Francisco — Private Practices
Jesse Dohemann, MD
Jon Kaiser, MD
Martin Mass, MD
Kenneth Mills, MD
William Owen, MD

San Francisco District Health Center #1
Nilda Alverio, MD
Jane Bailowitz, MD
Deborah Brown, MD
Toby Dyner, MD
Walter Krampf, MD
Lawrence Price, MD
Fred Strauss, MD
Ron Underwood, MD

Kaiser Permanente AIDS Research Unit — San Francisco
Jeffrey Fessel, MD
George Matula, MD
Jean Neuhauser, NP

Mission Neighborhood Health Center — San Francisco
Colleen Foy, MD
Ricardo Alvarez, MD
Steve Leiner, NP
James Smith, DO

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86)
Donald Abrams, MD
Gary Carr, NP
Molly Cooke, MD
Steven Deeks, MD
Stephen Follansbee, MD
Sandra Hernandez, MD
Mark Jacobson, MD
Neil Kudler, MD
Tony Lee, MD
Jill Legg, MD
Catherine Lyons, NP

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86), continued
Alexander Moy, MD
J. B. Molaghan, NP
Herminia Palacio, MD
Lauren Poole, NP
Laura Strauss, PA
Daniel Wlodarczyk, MD

East Bay — Private Practices
Robert Scott, MD

East Bay AIDS Center (Alta Bates Herrick Medical Center), Berkeley
Claire Borkert, MD
Carol Brosgart, MD
Steve O'Brien, MD

Highland General Hospital Adult Immunology Clinic, Oakland
Kathleen Clanon, MD
Walter Peters, MD
Deborah Royal, NP
Lisha Wilson, MD

North Bay — Private Practice
Milton Estes, MD

If you need more information about drugs and other treatments for HIV and AIDS, there are groups in the Bay Area that can help. Many of the people who are involved in these organizations are also living with HIV and have learned a great deal about the disease. They can help you learn, too, so you can fight it more effectively.

Access Project

1-800-734-7104
e-mail: AIDSTreatD@AOL.com
Internet: http://health.nyam.org:8000/public_html.network.index.html
A national clearinghouse for information about treatment access. For information about what drugs and treatments are available through federal, state or pharmaceutical-industry-sponsored programs, including:

- Medicaid and AIDS Drug Assistance Programs
- Patient Assistance /Expanded Access Programs
- Information about particular treatments.

ACT-UP Golden Gate Chapter / Treatment Issues Committee

Political action group. Committee works to reform treatment and drug development priorities and revolutionize the health care delivery system. Many members are very HIV knowledgeable.
Phone: (415) 252-9200 Information & announcements
(415) 252-9275 Office
Address: 519 Castro Street, San Francisco, CA 94114

AIDS Treatment News

Newsletter reporting on treatments for HIV / AIDS and public policy issues. Published twice a month. Subscription fee (available free or at low cost for people with limited income). Call for information. Highly respected.
Phone: (800) TREAT-1-2
(415) 255-0588
Address: P.O. Box 411256, San Francisco, CA 94141

Bay Area Perinatal AIDS Center (BAPAC)

Center at San Francisco General Hospital that studies transmission of AIDS from pregnant women to their unborn children. Good source of information about women with HIV/AIDS and pregnancy.
Phone: (415) 206-8919
Address: 1001 Potrero Ave., Room 6D1, SF, CA 94110

Brother's Network

Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to African-American gay, bisexual and transgender communities.
Phone: (415) 356-8140
Address: 973 Market Street, #650 SF, CA 94103

Drug Information and Clinical Trial Hotline

Free national hotline, in English and Spanish, for information about AIDS Clinical Trials. Hours are Monday through Friday, 6:00am - 4:00pm (California time).
Phone: 1-800-874-2572 (1-800-TRIALS-A)

Healing Alternatives Foundation

"Buyers Club" for products aimed at improving the health of HIV positive people and people with AIDS, including vitamins, minerals, herbals, nutritional supplements, experimental substances, foreign products and more. Good resource and information library to encourage client participation in their health care program. Library is free, Buyers Club costs $1.00 to join. Open 12:00 to 6:00 pm, Tuesday through Friday; 12:00 to 5:00pm Saturday.
Phone: (415) 626-2316
Address: 1748 Market Street, SF, CA 94102

HIV Research Consultation Clinic

A free service of the San Francisco General Hospital AIDS Clinic at Ward 86.
The goal of the research consultation clinic is to discuss the pros and cons of enrolling in clinical trials. The potential benefits and side effects of experimental therapies are also discussed. Referrals to enrolling trials in the Bay Area are made as indicated.
To make a free, one time only appointment with Steven Deeks, MD, call (415) 476-0828.

Living Well Project

Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Asian-American and Pacific Islander communities. English, Cantonese, Vietnamese, Mandarin, Tagalog and Khmer spoken.
Phone: (415) 575-3939
Address: 1841 Market Street, SF, CA 94103

Mission Neighborhood Health Center, La Clínica Esperanza

General medical care, clinical trials and social services for the Latino/a community. Bilingual (Spanish / English) staff.
Phone: (415) 431-3212
Address: 240 Shotwell Street, San Francisco, CA 94110

National HIV/AIDS Treatment Hotline

1-800-448-0440
For federally approved treatment guidelines and information. Calls accepted from people with HIV, families, friends, health care providers. All calls are confidential.

Native American AIDS Project

Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to American Indian community.
Phone: (415) 522-2460
Address: 1540 Market Street, #425, SF, CA 94102

Project Inform

Sponsors town meetings for information about and discussion of treatment twice a month. Information sheets and newsletter about available experimental drugs in treating AIDS, ARC, and HIV infection. Researches and disseminates information about where and how to obtain experimental drugs, current pricing, and what is known about dosage and clinical trials. California Hot-line. Free, donations for information sheets and newsletters accepted. Knowledgeable staff.
Phone: (800) 334-7422 (California only)
(415) 558-9051
Address: 1965 Market Street, San Francisco, CA 94103
Internet: http://www.hivnet.org/inform-www/index.html

Proyecto ContraSIDA por Vida

Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Latino communities, especially gay, lesbian, bisexual and transgender HIV positive people. Spanish and English spoken.
Phone: (415) 575-1642
Address: 3690 18th Street, San Francisco, CA 94110

San Francisco AIDS Foundation

Information and referrals to AIDS service organizations for people who need emotional or practical support. Spanish and Tagalog speaking staff. Publishes **BETA, the Bulletin of Experimental Treatments for AIDS**. **BETA** is published four times a year and has very up to date information on various aspects of HIV infection.
Phone: 1-800-FOR-AIDS (English, Spanish, Filipino)
(415) 863-2437 (**BETA** subscription info.)
(800) 327-9893 (**BETA**, outside SF)
Address: 10 United Nations Plaza, SF, CA 94102-6182

Trials Search

A free computerized clinical trials matching service that provides people with HIV with personalized lists of studies for which they may qualify based on their medical history. Database covers all open trials in California. To receive a report, complete the Trials Search questionnaire (found in this Guide or by calling the number below), or conduct your own search at the Trials Search site on the World Wide Web. Trials Search is a service provided by the Community Consortium.
Phone: (800) 492-5777
(415) 476-5777
Address: 3180 18th Street, #201, SF, CA 94110
Internet: http://www.library.ucsf.edu/aidstrials

WORLD
(Women Organized to Respond to Life-Threatening Diseases)

Newsletter contains updates about clinical trials and treatment information of interest to women. Organization sponsors "HIV-University" (HIV-U) to teach women infected with HIV about all aspects of HIV disease.
Phone: (510) 658-6930
Address: 3848 Webster Street, Oakland, CA 94609

Selected Medical Abbreviations:

< :	less than
> :	greater than
≤ :	less than or equal to
≥ :	greater than or equal to
qd:	daily
tiw:	three times a day
bid:	twice a day
PO:	by mouth
SQ:	subcutaneous (injected under the skin)
IV:	intravenous (injected in a vein)
IM:	intramuscular (injected in a muscle)
mg.:	milligrams
ml.:	millileters
mm.:	millimeters

Acquired Immunodeficiency Syndrome (AIDS): failure of the immune system believed to be caused by infection with the human immunodeficiency virus (HIV). The virus infects the body's cells that are essential to the proper functioning of the immune system.

Adverse reaction ("side effect"): toxic reaction to a substance. Common adverse reactions include rash, headaches, nausea, vomiting and drowsiness; and can be as severe as anemia, seizures and liver or kidney failure.

AIDS-Related Complex (ARC): a stage of HIV infection marked by symptoms such as swollen lymph glands (lymphadenopathy), chronic night sweats, recurrent fevers and unusual weight loss. Also commonly described as symptomatic HIV-infection.

Antibacterial: a substance which stops the growth of bacteria.

Antibiotic: a substance which kills or inhibits the growth of disease causing organisms, such as bacteria and fungi. For example, penicillin for some bacteria, amphotericin B or nystatin for some fungi.

Antibody: a protein produced by plasma cells in response to a specific antigen. Antibodies bind to antigens, often resulting in the inactivation of the antigen itself or the organism to which the antigen is attached. *See also* Antigen.

Antifungal: a substance which kills or inhibits the growth of a fungus.

Antigen: a substance, especially a protein, which stimulates production of antibodies.

Antiretroviral: a substance that stops or suppresses the activity of a retrovirus (for example, AZT, ddI, ddC). HIV is a retrovirus. There are now antiretroviral drugs that suppress HIV in different ways, such as protease inhibitors and reverse transcriptase inhibitors.

Antiviral: a substance that stops or suppresses the activity of a virus (for example, acyclovir, ganciclovir, foscarnet).

ARC: (abbreviation) *see* AIDS-Related Complex.

Asymptomatic: infection without symptoms. Someone may have HIV disease without showing any symptoms.

AZT intolerant: someone who has severe side effects when taking AZT and cannot continue taking it.

bDNA assay: a method of measuring directly the amount of HIV in a person's blood plasma. Also called "branched DNA"

Biopsy: removal of a small amount of tissue from the patient, either surgically or with a small needle, for microscopic examination to determine if disease is present.

Blinding: in research, refers to the process of preventing patients and / or their doctors from knowing whether the patient is taking active drug or placebo. *See also* Double-blind.

Bone marrow: soft tissue in the interior of a bone where blood cells are produced.

Bronchoscopy: examination of the bronchi (lung passages) with the aid of a bronchoscope (a tube inserted into the lungs).

Candida: a white, patchy fungus which often grows in the mouth or esophagus of people with AIDS, causing pain or difficulty in swallowing. Infection with *Candida* is known as "candidiasis" or "thrush."

CD4 cell: *see* T-cell

Central nervous system (CNS): the brain and spinal cord.

Clinical trial: a study which tests experimental medicines in human beings.

CMV: (abbreviation) *see* Cytomegalovirus.

Combination therapy (for AIDS): the use of two or more antiretroviral treatments in combination against HIV.

Glossary

Compassionate use: an FDA program that makes certain experimental drugs available to seriously ill people when no other treatment exists or when the patient cannot tolerate other treatments.

Cryptococcal meningitis: a fungal infection caused by *Cryptococcus neoformans* that affects the three membranes (meninges) surrounding the brain and spinal cord. Symptoms include severe headache, dizziness, nausea, loss of appetite, vision disorders and mental deterioration.

Cytomegalovirus (CMV): a virus that can cause aching, fever, mild sore throat, fatigue and enlarged lymph nodes. In AIDS, severe CMV infections can produce hepatitis, pneumonia, retinitis and colitis, leading in some cases to blindness, chronic diarrhea and death.

Diagnosis: determining the cause and nature of an illness.

Dose-ranging: drug trial in which different doses of a given drug are compared in order to determine which dose is the most effective and the least toxic.

Double-blind (double-masked): trial procedure in which neither experimental subjects nor doctors know which subjects are receiving the test drug and which are receiving a placebo or other therapy. This method is believed to promote faster and more objective results, as doctors' and patients' opinions about a test drug's efficacy might otherwise bias test results.

Efficacy: a drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

Encephalitis: inflammation of the brain.

Expanded access: (also called "parallel track") a procedure extablished by the FDA which permits the use of investigational drugs by individual physicians. The purpose of this program is to make the drug available to patients who need it, while collecting at least some limited data on efficacy and toxicity.

Experimental drug: a drug that is being tested for use as a treatment for a specific condition in a specific population.

FDA, Food and Drug Administration: The U.S. government department that approves and regulates drugs and medical devices. Pharmaceutical companies must have FDA approval to sell a new medicine.

Herpes: 1) a group of viruses including herpes simplex I (HSV I), herpes simplex II (HSV II), varicella zoster, Epstein-Barr virus, and cytomegalovirus. 2) a common name for blisters on the mouth or genital regions caused by herpes simplex I and II.

HIV: (abbreviation) *see* Human Immunodeficiency Virus.

HIV positive: having antibodies to the human immunodeficiency virus in the body. Implies infection with HIV.

Human Immunodeficiency Virus: a slow-acting retrovirus which many people believe to be the sole or foremost causative agent of AIDS and ARC.

Immune Thrombocytopenic Purpura (ITP): an autoimmune disease, in which the destruction of platelets (thrombocytes) leads to an increased susceptibility to bruising and bleeding.

Immunomodulator: a drug which alters, suppresses or strengthens the immune system.

IND: (abbreviation) *see* Investigational New Drug.

Infusion: the process of giving a substance (medication, food supplements, etc.) to a patient by injecting it into the blood stream. This procedure can either be a one-time event or continued over many hours, days or months.

Intramuscular (IM): injected into a muscle.

Intravenous (IV): injected into a vein.

Investigational New Drug (IND): term applied to an experimental drug after the FDA OKs testing the drug in people.

ITP: *see* Immune Thrombocytopenic Purpura.

Kaposi's sarcoma (KS): an abnormal proliferation of small, poorly formed blood vessels which occurs in some people with AIDS. KS lesions may first appear anywhere on the body or in the soft palate of the mouth; they may also remain hidden in the internal organs.

Lesion: a change in tissue caused by disease. A point or localized patch of a skin disease. Other words that mean about the same thing as lesion include "sore" or "spot."

Lumbar puncture (LP): insertion of a needle into the spinal column to remove spinal fluid or to inject anesthesia or medicine.

Lymphadenopathy: swollen, firm and possibly tender lymph glands. Causes may range from a temporary infection (such as the flu) to lymphoma.

Lymphoma: a malignancy (cancer) of lymphocytes, the cells that are responsible for normal immune function.

MAC (also called MAI): (abbreviation) *see Mycobacterium avium-Intracellulare* Complex.

Maintenance therapy: use of a treatment to maintain a desired effect that has already been achieved.

Malignant: used to describe cells or tumors growing in an uncontrolled fashion, either spreading to other sites through the blood stream or invading nearby, normal tissues. By definition, cancers are always malignant, and the term "malignancy" implies a cancer.

Mycobacterium avium-Intracellulare Complex (MAC): in people with AIDS, an infection which begins in the gut or lungs and is similar to tuberculosis. Later, the infection often spreads to other organs by way of the blood stream.

Neoplasm: tissue that grows more rapidly than normal; a tumor or growth. A neoplasm that does not spread to other tissues is described as benign. A neoplasm that spreads (metastasizes) to other tissues is termed malignant, and is commonly called cancer.

Neurological disorders: disorders of the central nervous system (brain and spinal cord), such as seizures or dementia, or of the peripheral nervous system (nerves) such as a neuropathy.

Neuropathy: the name given to a group of disorders involving nerves, whose symptoms range from a tingling sensation or numbness in the toes or fingers, to paralysis. "Peripheral neuropathy" refers to nerves outside the spinal cord, usually in the feet, legs, hands or arms.

OI: (abbreviation) *see* Opportunistic infection.

Opportunistic infection (OI): illness which would not normally occur in someone whose immune system is functioning properly.

Open label trial: (also called non-masked or non-randomized trial) a drug trial in which both doctors and subjects know what drug a subject is taking (and at what dose).

p24 antibody test: a test that measures the amount of antibodies in the blood against the p24 antigen.

p24 antigen test: a test that detects a protein fragment (p24) from HIV's core in blood and other body fluids. Not an accurate measurement of viral activity.

Pancreatitis: inflammation of the pancreas which can result in severe abdominal pain. Pancreatitis can be a side effect of a drug, but can occur due to including gallstones, viral infection and excessive alcohol intake.

PCP: (abbreviation) *see Pneumocystis carinii* Pneumonia.

PCR (Polymerase Chain Reaction) Test: A test to measure the amount of RNA or DNA (genetic material) of a virus or other organism in the blood or tissue. PCR tests are used to test HIV viral load.

Pharmacokinetics: the study of how drugs are absorbed, processed and eliminated by the body. This helps in determining the best route of administration, dosage and dosing schedule.

Phase I clinical trials: toxicity and dose-finding clinical studies which evaluate the drug's actions in the body, its safe dosage range, how it is absorbed, distributed, metabolized and excreted from the body. These trials are usually completed within a year and involve a small number of research subjects.

Phase II clinical trials: efficacy studies which often include several hundred human volunteers. They are designed to assess the drug's effectiveness precisely and to detect major adverse reactions (side effects).

Phase III clinical trials: involve up to several thousand participants to confirm earlier findings of effectiveness and to find side effects that occur only rarely or after a long period of treatment. They may last several years.

Placebo: an inactive substance against which test drugs (active or "real" drugs) are compared. In placebo-controlled trials the control group takes a placebo, while the test group takes an experimental drug. Many such studies are double-blinded so that neither the patients nor their doctors know which substance the patients are receiving. Placebos are usually harmless.

Platelets (also called thrombocytes): blood cells which help the normal clotting of blood.

Glossary

***Pneumocystis carinii* Pneumonia (PCP):** a type of pneumonia caused by a common parasite that grows rapidly in the lungs of people with AIDS. PCP is the leading cause of death in AIDS. Rarely, *Pneumocystis carinii* infections may occur elsewhere in the body.

PO: Oral; taken by mouth as pill or liquid.

Prophylaxis: treatment intended to prevent people from getting a disease. For example, aerosolized pentamidine and Septra® have been shown to be effective for prophylaxis against PCP.

Protease Inhibitor: an antiretroviral drug that prevents HIV from making copies of itself (replicating) by blocking an enzyme called "protease".

Protocol: detailed plan which states a clinical trial's rationale, goal, hypothesis, the drugs involved, dosage levels, methods of administration and treatment durations, as well as who may participate, their disease and its severity.

Radiation therapy: a treatment for cancer using radiation.

Randomized trial: in a randomized trial, participants are assigned by chance to receive one of the treatments being studied.

Rechallenge: to take a drug again despite previous bad side effects.

Refractory: severe disease that is resistant to treatment.

Remission: when the symptoms of a condition disappear. "Remission" is not the same as "cure," because a disease can sometimes come back after it has been in remission.

Renal disease: disease of the kidney.

Resistance: reduction in sensitivity to a particular drug.

Retinitis: inflammation of the retina, a part of the eye. In people with AIDS, retinitis is often caused by CMV or HSV infections. If left untreated, it leads in most cases to blindness.

Salvage therapy: treatment for patients who are non-responsive to or cannot tolerate other available treatments for a particular condition.

Side effects: an unintended effect. Some side effects are unwanted, harmful or poisonous (toxic), and are called "adverse reactions."

Spinal tap: *see* Lumbar puncture.

STD: sexually transmitted disease.

Study: a general term for any of a variety of research activities involving the collection, analysis or interpretation of data.

Symptom: any condition occurring because of a disease. For example, coughing is one symptom of *Pneumocystis* pneumonia, and headaches are a symptom of cryptococcal meningitis.

T-cells (CD4 cells): also called T4 cells or T-helper cells. The T4 cell enhances the immune response to an infection through a complex series of interactions with other types of cells.

Thrush: a *Candida* infection of the mouth and throat often found in people with HIV infection.

Toxicity: the degree to which a substance is poisonous. Clinical trials determine how much of a drug can be taken safely without having a toxic effect.

Toxoplasmosis ("toxo"): a disease caused by a parasite, *Toxoplasma gondii*, often involving the brain, eyes, heart, liver and lungs.

Vaccine: a substance that contains all or a portion of a disease-causing organism (usually "killed" by heat or chemicals) given for prevention or treatment of a disease. By stimulating production of antibodies, the vaccine helps to protect against infection by that organism.

Viral Load: the number of viral particles (usually HIV) measured in a sample of blood plasma. Viral load test results are given as number of HIV copies or equivalents (Eq) per millileter. There are two tests to measure viral load: PCR and bDNA.

Virus: microscopic agent which requires a living cell in order to reproduce. When viruses infect cells they can cause disease, often killing the cells they infect. Important viruses include Human immunodeficiency virus (HIV), Herpes and Cytomegalovirus (CMV).

Wasting Syndrome: progressive, involuntary weight loss associated with advanced HIV infection.

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Trials Search uses the confidential medical information you provide to us, and the study criteria given to us by researchers, to produce your personalized list of clinical trials.

Each study listing includes:

- Name of study
- Purpose of study
- What the study involves
- Who can join the study
- Whether the study pays participants
- Names and phone numbers of people to call if you want to join the study or ask questions.

How to receive your own Trials Search Report

On the reverse side of this page is a brief questionnaire that asks for information about your current health and your medical history. This information is matched with all of the clinical trials in our computer database. Within two working days of receiving your completed questionnaire we will send you a **Trials Search** report.

It is important to answer each of the questions completely. If you have problems filling out the questionnaire, call our toll-free number for assistance. Your doctor or other health care provider can also help. A nurse or medical office staff person may be able to answer these questions on the telephone.

Trials Search *is a service provided by the Community Consortium, an association of Bay Area HIV health care providers. The Community Consortium is affiliated with the UCSF AIDS Program at San Francisco General Hospital.*
Trials Search *was originally developed by Jay Seward and Brian Christianson of the Institute for HIV Research and Treatment at Davies Medical Center in San Francisco.*

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All information is mailed to you in a plain envelope. In some cases we may need to call you to clarify information on your questionnaire. Your name and other personal information is held in the strictest confidence.

NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

TELEPHONE _____ FAX (for response by Fax) _____

May we leave a message? ❒ yes ❒ no Is this a private Fax? ❒ yes ❒ no

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For your report complete BOTH SIDES and return by fax or mail to:

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3180 18th Street, #201, San Francisco, CA 94110
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Trials Search Questionnaire

Date Completed: ___/___/___ (mo/day/year) **Date of Birth:** ___/___/___ (mo/day/year)

Sex: ❒ Male ❒ Female **First initial & last initial:** _____ _____

Medical History:

CD4 Cell Count (T-helper cells): _____

Check the first column **(Past)** for each condition **you have had in the past,** but no longer have.
Check the second column **(Current)** for each medical condition that **you currently have.**

Past	Current		Past	Current	
❍	❒	Anal or Genital Warts	❍	❒	KS (Kaposi's sarcoma) - internal organs
❍	❒	Candidiasis - Esophageal (throat)	❍	❒	Lymphoma - Hodgkin's
❍	❒	Candidiasis - Oral (thrush)	❍	❒	Lymphoma - Non-Hodgkin's
❍	❒	Candidiasis - Vaginal (recurrent yeast infection)	❍	❒	MAC or MAI (Mycobacterium avium Complex)
❍	❒	Cryptococcal Meningitis	❍	❒	Molluscum Contagiosum
❍	❒	Cryptosporidiosis	❍	❒	Pancreatitis
❍	❒	CMV (Cytomegalovirus) - Retinitis	❍	❒	PCP (Pneumocystis carinii Pneumonia)
❍	❒	CMV - Gastrointestinal	❍	❒	Peripheral Neuropathy
❍	❒	Dementia	❍	❒	PID (Pelvic Inflammatory Disease)
❍	❒	Diarrhea - HIV Related	❍	❒	PML (Progressive multifocal leukoencephalopathy)
❍	❒	Hairy Leukoplakia	❍	❒	Syphilis
❍	❒	Herpes Simplex Virus	❍	❒	Toxoplasmosis
❍	❒	Herpes Zoster Virus (shingles)	❍	❒	Tuberculosis (TB)
❍	❒	ITP (Immune Thrombocytopenia Purpura)	❍	❒	Wasting Syndrome (unintended weight loss > 10%)
❍	❒	KS (Kaposi's sarcoma) - skin and mouth	❍	❒	Other:

HIV Medication History:

Check the first column **(Past)** for each medication **you have taken in the past,** but no longer take.
Check the second column **(Current)** for each medication that **you currently take.**

Past	Current		Past	Current		Past	Current	
❍	❒	3TC	❍	❒	Dapsone	❍	❒	Mycelex
❍	❒	Acyclovir	❍	❒	ddC	❍	❒	NAC
❍	❒	Alpha-Interferon	❍	❒	ddI	❍	❒	Nystatin
❍	❒	Amikacin	❍	❒	Diclazuril	❍	❒	Aero Pentamidine
❍	❒	Amphotericin-B	❍	❒	DNCB	❍	❒	IV Pentamidine
❍	❒	Atovaquone	❍	❒	EPO	❍	❒	Protease Inhibitor
❍	❒	Azithromycin	❍	❒	Ethambutol	❍	❒	Pyrimethamine
❍	❒	AZT	❍	❒	Fluconazole	❍	❒	Rifabutin
❍	❒	Bactrim/Septra	❍	❒	Foscarnet	❍	❒	Rifampin
❍	❒	Chemotherapy - local	❍	❒	Ganciclovir - IV	❍	❒	Sparfloxacin
❍	❒	Chemotherapy - systemic	❍	❒	Ganciclovir - oral	❍	❒	HIV Vaccine
❍	❒	Clarithromycin	❍	❒	Itraconazole	❍	❒	Other Antifungal
❍	❒	Clindamycin	❍	❒	Ketoconazole	❍	❒	Other Antiretroviral
❍	❒	Clofazimine	❍	❒	Marinol	❍	❒	Other Immune Modulator
❍	❒	d4T	❍	❒	Megace	❍	❒	Other:

*Allergies: **List all medications which you cannot take** because of allergies or serious side effects:

_____

Have Questions? Need Help? Call (415) 476-5777 (local) or 1-800-492-5777 (toll free).

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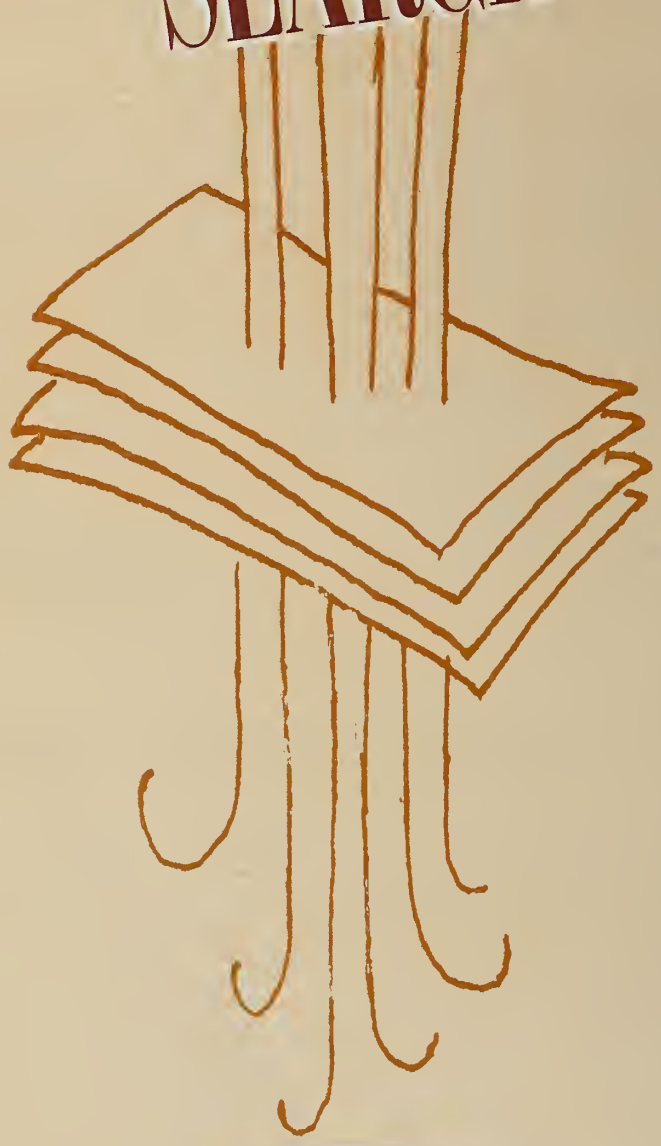

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